AGENDA
Department of Business and Professional Regulation
Drug Wholesale Distributor Advisory Council

Conference Call Number 888-670-3525
Conference Code 9259887749

May 19, 2016
9:30 a.m.

Council Members:
Gary Cacciatore, Pharm.D., J.D., Chair,
Primary Prescription Drug Wholesalers
Mike Ayotte, Vice Chair, Retail Pharmacy
Steve Mays, Primary Prescription Drug Wholesalers
Scott Brock, Pharmaceutical Manufacturers
Arlene Elliott, Agency for Health Care Administration
Dean Ellis, Secondary Prescription Drug Wholesalers
William Mahoney, Primary Prescription Drug Wholesalers
Patrick Barnes, Hospital Pharmacist
Michelle Renae Mendez, DO, Physician
Jeenu Phillips - Board of Pharmacy
Peter Hart, Medical Gas

DBPR Staff:
Reggie Dixon, Division Director
Division of Drugs, Devices and Cosmetics Program
Ken Lawson, Secretary
Tim Vaccaro, Deputy Secretary
Renee Alsobrook, Compliance Manager
Dinah Greene, Government Operations Consultant
Rebecca Burnett, Regulatory Supervisor
Amy Bennett, Office Manager

Call to Order: Gary Cacciatore, PharmD., J.D., Chair

TAB 1: Approval of Meeting Transcript- February 25, 2016

TAB 2: Chair’s Report – Gary Cacciatore, PharmD, JD

TAB 3: Division Director’s Report – Reginald Dixon

1. DDC Rules
   a. Legislative Summary - HB 941 & SB 1604
   b. Rules Report
   c. Tracking and Tracing - 61N-1.028 – 61N-1.032
   d. Applications - 61N-2
   e. Definitions – 61N-1.001

TAB 4: Other Business
Notice of Meeting/Workshop Hearing

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
Drugs, Devices and Cosmetics
The Division of Drugs, Devices and Cosmetics announces a telephone conference call to which all persons are invited.
DATE AND TIME: May 19, 2016, 9:30 a.m.
PLACE: Telephone conference: 1(888)670-3525, conference code: 9259887749
GENERAL SUBJECT MATTER TO BE CONSIDERED: General Business of the Council.
A copy of the agenda may be obtained by contacting: Dinah Greene, Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399, (850)717-1800.
Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 10 days before the workshop/meeting by contacting: Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399, (850)717-1800. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).
If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.
For more information, you may contact: Dinah Greene, Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399, (850)717-1800.
STATE OF FLORIDA

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

DRUG WHOLESAL DISTRIBUTOR ADVISORY COUNCIL

The above entitled Meeting convened at 1940

North Monroe Street, Tallahassee, Florida on the 25th

day of February, 2016, commencing at 9:30 a.m.

Reported by:

JEFFREY R. BABCOCK

Court Reporter
APPEARANCES:
REGGIE DIXON
STEVE MAYS
DEAN ELLIS
SCOTT BROCK
DINAH SKRNICH (GREENE)

TELEPHONIC APPEARANCES:
GARY CACCIATURE, CHAIR
ARLENE ELLIOTT
WILLIAM MAHONEY
PATRICK BARNES
JEENU PHILLIPS
PETER HART
PROCEDINGS

MR. CACCIATORE: This is Gary Cacciatore, I'm going to go ahead and call the meeting to order, and let's start with the roll call, Dinah, please?

MS. SKRNICH: All right. Gary Cacciatore?

MR. CACCIATORE: Present.

MS. SKRNICH: Mike Ayotte? Steve Mays?

MR. MAYS: Present.

MS. SKRNICH: Scott Brock?

MR. BROCK: Here.

MS. SKRNICH: Arlene Elliott?

MS. ELLIOTT: Here.

MS. SKRNICH: Dean Ellis?

MR. ELLIS: Here.

MS. SKRNICH: Bill Mahoney?

MR. MAHONEY: Here.

MS. SKRNICH: Patrick Barnes.

MR. BARNES: Here.

MS. SKRNICH: Michelle Mendez? Jeenu Phillips?

MR. PHILLIPS: Present.

MS. SKRNICH: And Peter Hart?

MR. HART: Here.

MR. CACCIATORE: Thank you, everyone, it sounds like we do have a quorum.

FOR THE RECORD REPORTING TALLAHASSEE FLORIDA 850.222.5491
MS. SKRNICH: You do.

MR. CACCIATORE: So the first order of business is the approval of the minutes. We've got an abbreviated minutes from the December 3rd meeting, but we also have a transcript that was provided later of the conference call that we had. Are there any edits or changes to the minutes? If not, I will entertain a motion to approve the minutes.

MR. BROCK: So moved.

MR. ELLIS: I second, this is Dean Ellis.

MR. CACCIATORE: Moved and second. Any discussion? Hearing none, all in favor signify by saying aye.

(Chorus of ayes.)

MR. CACCIATORE: Any opposed, like sign. Motion passes.

Okay, so as I usually do, I'm going to start out with reading our goals and objectives of our council. This is the Drug Wholesale Distributor Advisory Council of the Department of Business and Professional Regulation, my name is Gary Cacciatore, I'm with Cardinal Health and I serve as Chair of the council.

This council is charged with reviewing
Chapter 499 and the rules adopted under Chapter 499 at least annually, and provide input to the Department regarding all proposed rules to administer Chapter 499; make recommendations to the Department to improve the protection of prescription drugs and public health; make recommendations to improve coordination with other states' regulatory agencies and the federal government concerning the wholesale distribution of drugs; and make recommendations to minimize the impact of regulation of the wholesale distribution industry while ensuring protection of the public health.

And I think everyone can see by the items on the agenda today we're really working towards that goal of improving coordination, particularly with the federal regulations. And most of the agenda today covers legislation and rules to accomplish that goal, so I think we're moving in the right direction.

I don't have a particular report under Tab 2, so I'm going to turn it directly over to Tab 3, we've got a lot of information. I'll turn it over to Mr. Dixon to go through the legislation that's been changing on a daily basis, and then the
proposed rules that the Department has put out
regarding the track and trade. Mr. Dixon?

MR. DIXON: Good morning, thank you, this is
Reginald Dixon with DBPR. Just want to kind of
start off by going over -- as you can see, like
the Chairman said, we do have a lot of information
for you guys today. I guess we can start going
through the legislation.

I was going to jump around a little bit
because there's some of these bills that aren't
really going anywhere, and then we can get back to
the first two. Just to give you guys an update
on -- under 2016 Legislation C, House Bill 261;
House Bill 261 and Senate Bill 176 are both bills
that remove the cosmetic registration. As of
today, it does not appear that either of those
bills are -- will be moving forward.

The House bill was on a committee in January
and hasn't gone anywhere so far. The Senate bill
went to two committees, it last was in Senate
appropriations, but it was introduced in January
of 2016 and doesn't look like it has moved
anywhere at all. I'm not sure if those two bills
will move, or if some of the subsequent language
in those bills may be amended at some point later
to either the House or the Senate bill if it goes to the floor, which is a possibility. We don't have any indication that it would happen, it's just that those bills right now do not appear to be moving anywhere.

The same goes for Senate bill -- under E, Senate Bill 7038. That bill does not look like it was going anywhere as well. It was introduced in January and has not moved into any further committees.

For those of you who are unfamiliar with the legislative process, in Florida, each bill that is proposed has to go through three committee references. Once it gets out of those three committee references, you have to have a House -- or if it's a Senate -- if it's a House bill, it's got to have a Senate companion bill which both comes out of three committees a piece, and then go into conference or to the floor where those two bills are reconciled, and ultimately gets approved by the governor, and the language becomes law.

So with that kind of background, and like I said, that's a very-general background, I would like to move back to House Bill 1211. We're going to probably to spend the majority of the meeting
talking about Senate Bill 1604. The House Bill 1211 actually has gone through three committee stops, and is prepared to go to the floor.

In the agenda materials that you have in front of you, you have the House bill, and there were a number of amendments to that House bill. We can go -- we're prepared to go through the amendments, but just to give you a little bit of background, the -- as of yesterday on the Senate bill, there were four amendments that were filed last night by the 5:00 o'clock filing deadline, so to the extent that the House bill and the Senate bill need to be reconciled, what would probably happen -- and the Senate bill is being considered today at 10:00 o'clock -- if the Senate bill is approved with the amendments, and the Senate bill goes to the floor with the House bill that goes to the floor that does not have those same amendments, there is a lot of negotiation going on, but it is expected probably that the House bill will be amended -- there might be a strike-all which replaces the House bill with a bill which is identical to the Senate bill. So that's why I think the majority of the conversation might lay around the Senate bill,
because the Senate bill will have the most recent amendments.

Some of these amendments were amendments that were brought forth from folks in the industry who worked with our Division to try to reach a goal and try to solve the problems that may have come up inadvertently by the passage of this language.

So we can kind of go through the first amendment to the House bill. This first amendment it's on -- I'm sorry, I don't have page numbers on the agenda, but this first amendment basically allows the Department to adopt rules setting the limit on the amount of prescription drugs that can be distributed by a retail pharmacy before that retail pharmacy has to obtain either the retail pharmacy wholesale distributor permit; or alternatively, a wholesale distributor permit.

What this language basically says is that amount -- the limitation on what they can distribute is set right now at 3 percent, and that the Department has the authority to write a rule to basically define what minimum quantities is.

The hope with this amendment is that it would give the Department some flexibility so that if the federal government at some point came down
with a rule as they implement their DQSA and said, "Well, that limitation is 9 percent," well then the Department could then have the rule-making authority to write a rule that says 9 percent as opposed to having to go back to the legislature to get legislative authority to change it. So that's why it's initially set at 3 percent, and then gives the Department rule-making authority.

Did anyone have any questions about that amendment before I -- I thought it would probably be better to have -- to discuss the amendment and then ask for questions, and maybe we can do it that way.

MR. CACCIATORE: Mr. Dixon, is that restricted only to retail pharmacies?

MR. DIXON: Yes, sir. There's an exemption to the definition of wholesale distribution which allows retail pharmacies to distribute limited amounts of prescription drugs for office use, and "limited amounts" is not defined in the federal act.

And so the legislative staff thought it would be better for us to at least -- because we do have the retail pharmacy wholesale distributor permit, and if they're capped at 30 percent, the issue was
how do you reconcile that 30 percent with the --
limit with the retail pharmacy wholesale
distributor permit, and then also this exemption
to the wholesale distribution? And that's how the
legislative staff -- that 3-percent cap, at least
until the Department got rules done, was
specifically requested by staff from the Senate.

MR. MAYS: Mr. Dixon, this is Steve Mays, I
guess the section in the bill indicates minimal
quantities of a drug licensed -- drugs --
distribution of minimal quantities of drugs by a
licensed pharmacy to a licensed practitioner for
office use, so it would be limited to that?

MR. DIXON: Yes, sir.

MR. MAYS: Okay, thank you.

MR. DIXON: Where there any other questions
from council members? Mr. Chair, I'm not sure if
you -- is this the time that you wanted to open it
up for questions from anyone else that may be on
the line?

MR. CACCIATORE: Yeah, I guess that's better
to do it while we're talking about a particular
subject, rather than going back, so let's go ahead
and open it up to the public for any comments on
that as well. Anyone in the room there?
MR. DIXON: There doesn't appear to be any comments in the room, are there any comments from anyone -- any questions from anyone on the phone?

MR. CACCIATURE: All right, let's move on.

MR. DIXON: Okay. The second amendment here is more of a technical amendment. As you all know, under the DQSA, distributions by a manufacturer are no longer considered wholesale distributions. And so this is an amendment to strike the word "wholesale" from the provision in 499.01 which establishes our manufacturer permit.

So what this basically does is to just kind of line it up with some other provisions in 499 where now the wholesale distribution by a manufacturer is no longer a wholesale distribution. So that's why we just removed that term. Did anyone of the council members have any questions about that amendment? Did anyone on the phone have any questions or concerns or -- that they wanted to discuss about this amendment?

All right, I guess we'll move on to the third amendment. This third amendment is basically an amendment which it clarifies what the Division believes is the current law already in a sense that it allows the end-stage renal pharmacy to
distribute to a commonly-owned end-stage renal pharmacy prescription drugs to meet the immediate emergency need of a patient. And then it gives the Department the authority to develop rules to say when those distributions exceed what you would normally be considered meeting the emergency need of a patient.

In a sense, if you've got two facilities that are commonly-owned, and a patient comes in and during the course of that treatment, that patient runs out of medication and they need it immediately, it should not be such that a facility is afraid to ship it from one of their sister facilities because they don't have the restricted distributor permit which facilitates that distribution.

We've always taken the position at least that -- at least from, I know, since I've been here, I know that a pharmacy is allowed to do an emergency distribution to another pharmacy to meet the immediate need of an identified patient. So we wanted to make sure to clarify that because we were approached by a group representing the end-stage renal dialysis folks, and so we wanted to make sure that -- they wanted to make sure that
this was clarified, so that's why this is in the law, which is -- this is why this amendment came about.

Are there any council members that had any questions about this amendment? Is there anyone on the phone on the conference call that may have had some questions about this amendment?

MR. CACCIATORE: None here.

MR. DIXON: Okay. The fourth amendment deals with distributions of repackaged medications by rural hospitals. One of the things that this bill does is it actually allows -- it relieves some of the requirements on the rural hospitals that have the restricted distributor permit who want to repackage prescription drugs for those rural hospitals.

And so what this amendment does is it gives the Department rule-making authority to implement rules or to adopt rules that deal with those drugs that are being repackaged by rural hospitals in a sense that, even though we lessen some of their burdens, we do want to be able to have, and we thought it was appropriate to have, some rule-making authority so we can set some standards just to ensure that the safety of those
prescription drugs, and the patients that they serve, is not compromised. So that's how that came about.

Are there any questions from any council members on that amendment? Were there any questions from anyone on the conference call about the amendment?

Okay. So just kind of re-cap, those amendments have already been incorporated into what is now -- and let me make sure I have this straight -- it is now called -- the current House bill is the Committee Substitute for -- it is the Committee Substitute for the Committee Substitute House Bill 1211. So that's -- so if anyone wants to take a look at that, go online and look at it. If you go onto the Florida House of Representatives' page and you type in House Bill 112 (as spoken), the most-recent version of it is the Committee Substitute for the Committee Substitute for House Bill 1211, okay?

Moving on to the next -- the next bill is actually the committee substitute for House bill 1604 --

MR. BROCK: Senate bill.

MR. DIXON: Oh, I'm sorry. It's Committee
Substitute for Senate Bill 1604. Okay. That particular bill, as I said, there were four amendments filed last night to this particular Senate bill, and we can go through those amendments rather quickly.

And some of these amendments are just to bring the Senate bill into alignment with the House bill. For instance, the first amendment is the amendment dealing with the minimum quantities by prescription drugs distributed by retail pharmacies. So this is same amendment which sets that limit at 3 percent and then gives the Department rule-making authority to determine what that limit should be.

The one nuance that should be noted in this amendment is it sets that 3 percent to 3 percent of the retail pharmacy's total annual purchases; whereas in the House bill it didn't have language "retail pharmacies," so there may have been some confusion as to whose purchases that 3 percent was limited to.

In other words, was that 3 percent limited to the purchases by the practitioners, or was that 3 percent limited to the purchases by the retail pharmacy? And so that phrase "of the retail
pharmacy's total annual purchases," was included in that amendment.

Were there any questions about that amendment from anyone on the council? Any questions from anyone on the phone?

Okay. The second amendment to the Senate bill is the one that talks about the end-stage renal pharmacies. It's the same language that allows them to distribute between commonly-owned end-stage renal pharmacies to meet the emergency need of a specified patient, and it also gives the Department the same rule-making authority.

Were there any comments from anyone on the council, or questions about it? Any comments or questions from anyone on the phone about it?

Okay. The third amendment is the same amendment that talks about the distribution of repackaged drugs by rural hospitals. Were there any comments or questions from anyone on the council regarding that amendment? Were there any questions from anyone on the phone about the amendment?

The fourth amendment is actually a little bit different. The fourth amendment is an amendment which actually talks about --
those basic business records that need to be maintained by those entities that are regulated under Chapter 499.

There was some -- and just to give you a little bit of background, there was some concern that the provisions under Section 499.0121(6) which talks about record keeping, there was some concern that those provisions may have conflicted with what the federal law says with respect to tracking and tracing.

The difficulty here, quite frankly, is that our statutes deal with both the prescription drugs and the API, and the subset of the prescription drugs is a product which is addressed under the product tracing and -- tracking and tracing requirements under the DQSA.

So we worked with the industry to try to come up with language which set out the record keeping requirements that said, "Look, these are the records that you ought to have. These are basic business records. We didn't want you to create and maintain anything that you wouldn't normally create. So you should know your sources, you should know if they're licensed. You should know where the drugs are actually physically coming
from. You should know what the drugs are. You should know how much they cost and how much of it that you received, and what you did with it ultimately."

So those basically are what the requirements are. There's a requirement that you be able to run an inventory -- which you would think any business could run an inventory of what it actually has -- and there's also a provision in this new statute that basically says to the extent that those basic business records that you are keeping, the information contained in those is subsumed or contained in the DQSA tracking and tracing requirements, then you only have to follow the tracking and tracing requirements, because that's what you're supposed to do.

And the point was not to have record keeping provisions that are in addition to, in contravention of, et cetera, et cetera, of the requirements of the DQSA, at least with respect to those products. If it's not a product, then you have some basic record keeping requirements that shouldn't be a onus because it's kind of expected those are the records that you would keep anyway.

Are there any questions from the council
members about that, because I know this amendment is -- was late-filed yesterday. I know we did have some conversations with the folks from HDMA about these, but I'm not sure if everyone from the council had an opportunity or if the people from the industry had a chance to actually fully look at this language.

MR. BROCK: Reggie, just to clarify, make sure I understand what you -- the comments you just made, if your product is covered under the federal act, then you follow those record-keeping requirements under the federal act.

MR. DIXON: Yes, sir.

MR. BROCK: If it is an API or a prescription drug that is not covered under the federal act, then this language would apply.

MR. DIXON: Yes.

MR. BROCK: Okay, thank you.

MR. DIXON: Were there any questions from anyone on the phone? Okay. Well, and again these amendments have not yet been incorporated into the Senate bill, it is expected that they will be today. The Senate bill is up before -- the Senate bill is on the Senate Appropriations Committee meeting agenda at 10:00 o'clock this morning, so
we expect that these amendments will be
incorporated into the Senate bill, so we want to
make sure we brought those to your attention.

I guess we -- if we didn't have any questions
regarding any of the other legislation, we can
move on to the tracking and tracing rules that we
have in front of you today.

I just kind of want to start off by giving
you the general background. I know the council
members have heard us say this before at different
meetings, but what we wanted to do and -- what we
wanted to do and I think what we were required to
do is to implement the federal rules as much as we
could into federal statute -- the federal statutes
into our Departmental rules, I'm sorry -- in the
sense of this: There's a provision under Florida
law which prohibits the state from delegating rule
authority to entities outside of the state.

And so it was a difficult thing to try to do
in the sense that we realize the tracking and
tracing set standards that are statutorily set at
the federal level, but we also realize that the
FDA has to actually go through and do their
federal rule making to further define, further
implement those federal statutes.
And so the difficulty that we have from the divisional standpoint is getting legislation through the legislature is not always the easiest and the best -- the quickest process. And so what we wanted to do was, instead of putting the federal statutory requirements in our statute, to put those requirements in our rules. And so as the federal government goes through its rule making, then we can go through our rule making to further clarify, like these product tracing and -- tracking and tracing requirements.

And of course, as we go through rule making, similar to what we're doing today, the rules come before the council, the rules get published in the FAR, interested parties can call in, can request a hearing. We can do a workshop, we can do a bunch of different things to get industry input to make sure that our rules are where they need to be at so that we're compliant with the DQSA.

Had we done this in statute, we would not necessarily be able to have that flexibility, so that was the purpose for putting these tracking and tracing requirements in our rules, as opposed to actually sticking them in the statute.

And what you'll see is, in addition to the
tracking and tracing requirements, we actually incorporated the federal definitions as well into our rules with the thought that, as the federal folks go through and implement it, we will be able to be more responsive, and you won't have -- like we did with the implication of the DQSA, you won't have a two or three-year gap where you've got a federal statute in place, and then the federal -- and then we are, as an agency, are trying to catch up to what the current federal law says.

So without further ado, I guess we'll start with the first proposed rule. We have 61N.028 (as spoken.) What this rule attempts to do is to bring in the federal definitions for the purposes of tracking and tracing products.

And let me back up. Procedurally where we're at right now is, in Florida, what you have to do is you have to do what's called a notice of rule development where you open up the rule, and you say, "Hey, look, we're going to be doing rule making in this area." Once we say we're going to be doing rule making in this area, you have to come up with language and then you tell the public this is the proposed rule. So we file what's called a notice of proposed rule where we actually
put the language out to the public for comment.

So right now, we're at the point where we have notice of language, and we've put the language out there for comment. And so if we don't receive any comments, if we don't receive, like, a hearing or we don't have -- or we don't make any changes, these are what the rules are.

So it's really important that, to the extent that there are changes that need to be made to the rule -- things that may not be in compliance with the federal act, things that we have missed -- it's very important that we have that input now rather than later.

So we do ask that, to the extent that you can, if there are issues that you see with these -- some of them couldn't be avoided, and I think we may know what some of those are -- but if they're ones that we can fix, things like that, this is a very-important time for us to try and do that; because otherwise, we may end up with rules that are in place and then the folks wouldn't be able to comply. And we do not want people to be in a position of noncompliance right from the bat because we failed to do something in our rule making part.
MR. CACCIATORE: Mr. Dixon?

MR. DIXON: Yes, sir.

MR. CACCIATORE: This is Gary Cacciatore.

And just to clarify on the procedural aspects, these rules were published, I think, on February the --

MS. SKRNICH: 17th.

MR. CACCIATORE: -- 17th, and there's a 21-day time period where the public can request a hearing on the rules; correct?

MR. DIXON: Yes, sir.

MR. CACCIATORE: I thought -- is that same 21-day time period apply to written comments or was it a different time period for that?

MR. DIXON: What we can have -- and there's a difference between comments and folks who request the rule -- like a workshop. A workshop is where -- let's say today someone -- we decided that there's not enough time to kind of go through this stuff and vet it, or if someone later on determines, "Hey, look, this impacts me in a way that it shouldn't because the federal statute says X, Y, and Z," the best way to ensure that your input is gathered that -- is to request a workshop. And it's not some big formal thing that
you have to do, you can just write in and say you request a workshop, and what we would have to do is we would suspend rule making -- well, not necessarily suspend rule making, we would actually notice another meeting where then the specific content of whatever particular rule is at issue would be brought up and it would be further vetted.

And if that after that workshop a determination is that changes need to be made to that rule, what we would have to do is we would have to file what's called a notice of change which would actually be a notice changing the language to address whatever comments or concerns we receive from those parties who are effected by the rule.

But if we don't get any of that comments, we have to review those comments and determine whether or not those comments subsequently change the rule. Like if someone just rolled in and said, "Hey, look, you know, we don't necessarily like the formatting of the rule, we wish you had renumbered it a different way," that's a comment that we would accept, but we wouldn't have to do anything with it.
If someone wrote in and said, "Hey, look, I think the way this rule is written is different and it adversely impacts, and it's going to cause a financial strain on our business to do X, Y, and Z," that's a substantive comment that I think, as a Division, we have an obligation to maybe do a workshop and then bring that back to the council and say, "Look, here's a comment that we received. Here's a response; here's the Division's; we've done an analysis, and we think maybe the person's off here, or maybe they're right on," and we've tried to come up with a different language to address that.

So that's kind of the process that we have to go through so that -- you know, the last thing you want is someone to challenge the rules and say that you didn't have an open proceeding and you didn't follow the appropriate procedure for actually adopting rules.

MR. CACCIATORE: Okay, thanks. I just want to make a courtesy -- make sure all the council members and members of the public understand that if you have comments, this is -- as Mr. Dixon said, this is the time, either to express them verbally through the council here, or to submit.
formal comments. Or if you think it's a major
issue and want to request a workshop or something
like, then that's the proper procedure to do that.

MR. DIXON: And you'd have -- and just a
reminder, I think it applies per rule, so you
would want to do that per rule. So if you had a
question -- let's say you had a question about
only the definitions, and you didn't -- and no one
had any questions about anything else, the other
rules could possibly go into effect, and then we'd
still be working on the definitions.

So I think if you have questions, you know,
or you have comments, or you have issues that we
need to resolve, it's best to kind of do it now or
subsequent -- rather sooner than later, maybe
that's a better way to say it.

MR. CACCIATORE: And just to clarify so
everyone understands, if there is a rule hearing,
that's run by the Division. The Division does a
great job of working with the council, but
remember we're an advisory council, so we don't
actually decide and vote on the specific language,
we can only make recommendations to the Division.
But fortunately they work with the council.

So as Mr. Dixon said, if there is a major
issue, he may bring it back to the council; but any rule workshop would be held by the Division as a separate meeting.

MR. DIXON: So with having said that, the first rule that we have is 61N-1.028 -- or the proposed rule -- and as I indicated, what we tried to do in this rule was to incorporate the definitions that are set forth in the DQSA.

Normally, when we do something like this, we don't necessarily go through line-by-line, unless -- what I think would be a better idea, unless, Mr. Chair, you want to do it differently, was to ask for any comment on a specific part -- either the rule in general, or specific sections of the rule -- and then we can try to address those one at a time.

MR. CACCIATORE: Yeah, I think that makes sense, especially for this particular section, we just ask if anyone has any comments on any particular issue with any particular definition.

MR. DIXON: Were there any comments or questions from anyone on the council regarding 61N-1.028?

MR. BARNES: Mr. Chair, this is Patrick.

MR. CACCIATORE: Go ahead, Mr. Barnes.
MR. BARNES: So just reviewing this, it looks like we've done a really good job, Reggie, on kind of trying to mirror it. I know one of the issues that, at a national level, some of the pharmacy organizations are working with the FDA on drug shortages as far as when a hospital needs to transfer a product -- or the borrow-and-loan process like -- if you will, on that, where you're -- you may need to transfer a limited supply to take care of a patient.

And so far there hasn't been anything back from the FDA on that, and I guess I'm assuming that if the FDA comes out with something on that, that the State of Florida would then mirror what the feds are doing in that regard. That would probably be a true statement, do you think?

MR. DIXON: I believe so. It would just depend -- like I said, without knowing exactly what the language would be, I think the best answer I can give is we would do whatever we could to try to come into compliance with the federal act as long as it's not something that is just outright violative of Florida law.

For instance, if it's something that we need a statutory change, I don't know that, by rule, we
can do something that would require statutory
change, but I mean, you know, that's obvious now.

MR. BARNES: So one of the things that I hear
is having -- under the exemption phase, Number 4,
the dispensing of a product pursuant to a
prescription executed in accordance with 21 U.S.C.
and so on and so on. Could that be referred to as
an order -- prescription or order?

MR. DIXON: I'm sorry, what page are you
referring to? What line are you referring to?

MR. BARNES: This is 61N-1.028 on the second
page.

MR. DIXON: Okay.

MR. BARNES: Number -- let me find it again.
I'm sorry, the last page under exemptions, so
that's 25, which is transaction. And then
there's -- D talks about exemptions. So
exemptions to the term transaction does not
include. Do you see that?

MR. MAYS: B4, I think.

MR. DIXON: Okay. Yes, sir.

MR. BARNES: And then Number 4 talks about
the dispensing of a product pursuant to a
prescription. So what -- I know in the retail
setting what a prescription is, but what about in
a hospital setting? Could that be interpreted as
an order?

MR. DIXON: I think that the definition of
prescription, I want to say, is under 456, and I
think it is also under 893. And if I'm not
mistaken, I think that does include an order from
a physician.

MR. BARNES: Okay, very good.

MR. DIXON: I'm going to -- while we're
talking about it, I'm just going to look it up
real quick just to make sure, but I want to say
that that is a yes. Are there any other
questions -- I guess, while we're looking that up,
were there any other questions about the
definition -- about this particular rule?

MR. MAYS: Yes, this is Steve Mays. Under
definition on Number 26, Transaction History, the
last sentence states "transaction history for a
grandfathered product begins with owner of the
product on January 1st, 2015." The FDA has
extended by enforcement discretion accepting that
history by wholesalers up until May of 2015; and
then actually for dispensers, it's next week,
March 1st.

So I'm just wondering if that's going to
cause issues for the Department as far as enforcement, and I'm not sure about your authority to exercise that same enforcement discretion.

MR. DIXON: That's actually a very good question, because what we did was we took this language to try to mirror what the DQSA says. So we -- that may be one we definitely need to consider. If they're exercising enforcement discretion, what we may be able to do is -- if we leave the language, what we may be able to do is if it comes across, if it's applied to someone, they may be able to maybe receive a waiver of the rule. But I don't know if -- if changing that may be not -- changing that date may not be a big deal either, because it isn't a rule.

MR. MAYS: Yes, because I think the industry -- as of January 1st, the industry -- it was found to not be ready to exchange that data, and in fact, probably there were some manufacturers that weren't even passing that data as of January 1st, 2015, so it's pretty much the entire supply chain. So it would -- I can see it being problematic for a pharmacy if you go back to look to see if they're accepting that data before March 1st of 2016.
MR. DIXON: Okay. I'm going to note on here that we need to come up with a new date, because what we may be able to do, if -- well, let's discuss it a little bit. If we came up with a new date, are there any thoughts as to a date? Like maybe do you think it would be, like, July 1st or something? Could the date that -- did the FDA give a date for --

MR. MAYS: Yeah, they publish those dates, and I mean, my recommendation would be to adopt those dates for the different supply chain members. I think, you know, like May 5th -- I think it's May -- I'm not positive, and Gary, maybe you know -- I think it was May 2015 for wholesale distributors, and then March 1st, 2016 for dispensers.

MR. CACCIATORE: That sounds right, I -- I think if you went with a March 1st, 2016, that would cover --

MR. MAYS: That would cover the whole -- if you wanted to do it that way.

MR. DIXON: Okay. So March 1st -- so we think March 1st, 2016 would cover everybody?

MR. MAYS: Yes.

MR. DIXON: Okay. So that may be a good idea
just -- we just -- we change the date to March 1st, 2016, then you don't have to worry about anything that's before that.

MR. MAYS: Right.

MR. DIXON: Okay. I'll bring that back to our folks and see, because changing that date now before the rule goes into effect is probably a very good idea. Okay. All right, I'm sorry, I'm just looking real quick --

MR. CACCIATURE: This is Gary Cacciatore, just a comment reflecting Patrick's question, and this is on Section 30, definition of Wholesale Distribution. Subparagraph (c), because Mr. Barnes talked about meeting the needs of a patient, this is emergency medical reasons, but I guess I'm a little concerned about this only addresses a public health emergency, so it doesn't really address Mr. Barnes' concern about an emergency for a particular patient, so Mr. Barnes is that language there going to be problematic for a hospital in an emergency situation in a drug-shortage situation?

MR. BARNES: Yes, Mr. Chair, this is Patrick. That's exactly the concern that pharmacies have. At a national level, we're working with the FDA
to, you know -- I mean, these drug shortages are certainly real, and there's times when we then, for emergency situations for a patient, we need to borrow product.

So it's pretty clear in the federal regs that these transactions are not exempt, and so we're still working with the FDA to see what can be done about it, and I think some of the things that people are doing, there's really a couple different kinds of, in my opinion, borrow-and-loan transactions: One could certainly be a drug that another entity certainly has enough product and it's really not a patient-specific transaction. And then in cases like that, you would probably need to pass on the T3 information.

But sometimes you're just needing a couple doses until you can do an order for that product yourself; and in those cases, that's more of a patient-specific transaction. Or -- and that's where I wanted to get the definition of prescription, as far as that construed as an order, and I think a lot of us are considering a prescription and an order as the same.

MR. CACCIATORE: That's made for those types of situations you believe, right, I --
MR. DIXON: Hi, this is Reggie. The definition for prescription under Florida law right now is contained in Chapter 893. Specifically it's 893.02, and it's Paragraph 22. It's pretty-long paragraph, but what it starts off by saying is "Prescription means and includes an order for drugs, medicinal supplies written, signed, or transmitted by word of mouth, telephone, telegram, or other means of communication by a duly-licensed practitioner licensed by the laws of the state to prescribe such drugs and medicinal supplies issued in good faith, and in accordance of professional practice intended to be filled, compounded, or dispensed by another person licensed by the laws of the state to do so, and meeting requirements of section 893.04."

So I think that will -- I'm sorry it took a minute to get that, but I think it does cover the situation that you were talking about, Patrick.

MR. CACCIATORE: Mr. Dixon, isn't 893 only for controlled substances, though?

MR. DIXON: 893 -- it deals with controlled substances, but to the extent that it has a definition of prescription drug, that definition
does not necessary -- is not limited to just
controlled substances.

MR. CACCIATORE: Okay, thank you.

MR. PHILLIPS: Gary, this is Jeenu Phillips, 
if I can speak?

MR. CACCIATORE: Yeah, Mr. Phillips, go
ahead.

MR. PHILLIPS: Yeah, so -- and it's not only
in 893, but also in 465.003 under definitions, and
it also includes -- it includes a definition of a
prescription. "Prescription includes any order
for drugs or medicinal supplies written or
transmitted by any means of communication by a
duly-licensed practitioner authorized by the laws
of this state to prescribe such drugs or medicinal
supplies, and intended to be dispensed by a
pharmacist" --

MR. CACCIATORE: Okay, thank you --

MR. PHILLIPS: -- continues and goes on from
there --

MR. CACCIATORE: -- that helps.

MR. DIXON: Okay, I'm sorry. So right now
with respect to 1.028, I think we did have -- we
had the one question with respect to the
grandfathering. I think the idea is to possibly
do a notice of change with respect to that date.
And I think -- and Patrick I hope we answered that
question with regards to whether or not a
prescription included an order.

Were there any other comments or questions
from council members regarding the definitions, at
least in 1.028? Were there any questions or
suggested changes from anyone on the phone?

Okay. Well, again, like I said, we are
actively looking for, with respect to any
suggested changes that there may be from anyone on
the phone, as well as anyone on the council.
Again, I just want to reiterate that it is really
important that we kind of get input as early as
possible so that we can give some clarity and
some -- to the industry as to what the tracking
and tracing requirements are.

Okay, so I guess we'll move to 61N.029 (as
spoken) Manufacturer Requirement. Are there any
questions or concerns or comments with respect to
these from any of the council members? Were there
any questions or concerns with respect to 1.029
from anyone on the phone or anyone on the call?

All right. Okay, I guess we're moving to
61N-1.030, Wholesale Distributor Requirements.
Are there any questions from anyone on the council regarding those requirements that we -- in the rule as drafted? All right. Are there any questions from anyone on the phone regarding the language that's included for wholesale distributor requirements?

Okay, so we're moving to 61N-1.031, dispenser requirements. Were there any questions or comments from anyone on the council regarding the rule drafted for the dispensing requirements?

MR. BARNES: Yes, Mr. Chair, this is Patrick.

MR. CACCIATURE: Go ahead, Mr. Barnes.

MR. BARNES: Reggie, so I guess part of the issue, I think, is the -- eventually everything will be electronic, and -- for all this T3 information -- and that's certainly, you know, slated to start, I believe it's July 2017, but it probably will subsequently be delayed.

But really right now the electronic solution is not fully-baked yet. I've spoken with many of the hospitals that are getting involved, and it's just not there. And I guess my main thing is when -- right now, most of your product is purchased from wholesalers, and wholesalers are storing that T3 information from the dispensers. You still
have to have mechanisms in place for products
outside of that, which would be a direct order, or
drop ships, which right now mainly is paper, but
eventually will be electronic as well.

So I guess my real question really gets down
to when the state inspects a pharmacy and pulls a
product off the shelf, what will they be looking
for? Is that something to be decided? Because
I'm not going to be able to tell -- you know, I'm
going to default to that I purchased it from the
wholesaler, but lot number is not part of that T3
information yet, and that's not going to go into
effect until serialization, so is there any idea
on what's going to be required then?

MR. DIXON: That is actually part of the
training that we have to go through when we talk
about -- when we work with our folks in the field.
I think everyone -- well, at least anyone who's
been looking at this, we all understand the
information that's contained and that's not
contained, and what will be available at the time
of doing the inspection. So probably the only
thing our folks will be looking for is information
that is available and that's required to be
maintained.
So for instance, if you're not required to
get it, it wouldn't make sense -- at least I would
hope it wouldn't make sense -- for us to ask you
for something that you shouldn't have.

And so I think that under this requirement,
to the extent that you've got an agreement with a
wholesaler to maintain that information for you,
it may be as simply as asking you as the -- or
whoever the person is at that facility, to contact
the wholesaler and get whatever information they
have, and then to provide that information to the
inspector.

I think it would be inappropriate for an
inspector to ask you to produce information when
we know that the information isn't included in the
T3.

MR. BARNES: Well, if I could suggest maybe
at a workshop when you're thinking about
developing all that and including wholesalers and
then dispensers, just to go over the information
that's out there and just so we're -- to kind of
get it all in the open, and then, say, maybe the
Department could get a good understanding of what
is out there and then go from there. If I could
suggest that.
MR. DIXON: Let me just -- I just want to make sure, because I think that there may be a little bit of a difference between actually doing a workshop versus having a public meeting.

A workshop is where you have an issue with a particular rule, and I don't necessarily know I hear you saying that there's an issue with the rule, as much as how we work with and train our inspectors regarding the information that's available to you guys on -- as recipients of the product. I think that that would -- may be more of an open public meeting where -- or maybe where we have meetings with folks who represent the industry participants, maybe Florida Health System pharmacies, or other entities like that who are the end users, where we can bring them in, they can give us examples of some of the concerns that they have, and then we can use that to help maybe train our inspectors in the field of what to look for, if that seems to be more of an appropriate avenue.

MR. BARNES: Yeah, that sounds fine.

MR. DIXON: Okay, well let me -- I'm going to just make a note so that that may be -- because we can do that pretty easily.
MR. BARNES: Great. I can get with you later, Reggie, and we can set that up.

MR. DIXON: Okay. Like I said, I just want to make sure I have -- I'm making a note on it. Okay. Were there any other questions or maybe comments or concerns about the language for 61N-1.031 for the dispenser requirements? Was anyone on the line, other than a council member, who may have some questions or concerns about the language?

Okay. Well, I think the last rule that we have is 61N-1.032, which is a product tracking and tracing for repackager requirements. Was there any comments or concerns or suggestions from the council members on that particular language? Any comments or concerns from anyone on the phone?

Okay. Hearing no further comments, I just want to back up just a minute before we kind of conclude this portion of -- and again, for the record, it's really important for us as an agency, as a regulatory department, to get as much input and feedback as we can from the regulated industry that helps us to make sure that we're not overly-regulating or passing or writing rules that we think are contrary to federal law, and contrary.
to what folks in the industry can actually comply with.

These rules will be noticed, I think it -- is it 40? Is it next 30 days? And so in that timeframe, we're going to be asking folks if you have comments or something that come up after that, you can send those directly to me or to Ms. Greene. My email is included -- both our emails, I think, are included -- at least our contact information is included in the notice of proposed rule.

My email -- I thought it was on here -- but my email for the record is Reggie, R-e-g-g-i-e, dot Dixon, D-i-x-o-n, @myfloridalicense.com; and Ms. Greene’s email is actually on the notice of rule, which is Dinah, D-i-n-a [sic] dot Greene, G-r-e-e-n-e, @myfloridalicense.com.

To the extent that anyone, if you share a rule with someone and they may have a comment or they may have some concerns and may request a notice of hearing, please submit those to either Dinah or myself. We will go through those and try to vet those as quickly as we can, and if we need to have another council meeting, we will try to set one up. If we need to have a workshop, we'll
set one up and we'll do the notice and all those other things.

    Right now, my take-away from at least the suggestions that we have that we received is that with respect to 1.028, specifically sub -- at least Paragraph 26 when it speaks to transaction history, that the second line of that where it says "The transaction history for a grandfathered product begins with the owner of the product on January 1st, 2015," that the FDA has began using -- has exercised enforcement discretion and that we think -- or that the council members think that if we change that date from January 1st, 2015, to March 1st, 2016, that that would address the concerns hopefully of everyone in the industry, or at least in the supply chain.

    Is that -- and that's the only suggested change, I think, that -- that's the only suggested change that we have coming away from at least this particular meeting. Were there any others that we didn't get from anyone on the council or anyone else in the audience or maybe on the phone?

    Okay. Well, I think we can work with our staff to kind of see if that's something that we can do. I don't think that will be an issue, we
may be able to just file a notice of change on that pretty quickly.

Mr. Chair, I think that we have concluded at least the portion with regards to the director's report. I think that under other business Ms. Greene may have some questions about our meeting schedule.

MR. CACCIATURE: Thank you, Mr. Dixon. Let's turn -- before any other business, I'll turn it over to Ms. Greene.

MS. SKRNICH: I just want you to be thinking of a future date for February of next year, and changing it, maybe, to March.

MR. DIXON: And just for the record, we -- in Florida they don't have a special session -- we don't have an early session every year. I think I attended a meeting about two weeks ago where the thought process was that they would have a January-type of session like this year every other year. So next year is probably expected that session will actually start, I think, in February or was it March?

MS. SKRNICH: March.

MR. BROCK: March.

MR. DIXON: March. So next year it will be
March and April, so -- February may be difficult because of the weather and stuff, but maybe, you know, you won't have people running with session in February so --

MS. SKRNICH: We just seem to have issues with having attendance in February.

MR. CACCIATORE: Yeah, I'm just curious if that's a weather issue, or is it just difficult with the session going on or what the issue is with February. Let me ask the other council members, we've got four meetings a year, we do two in person, generally they've been, what, February and --

MR. ELLIS: August.

MS. SKRNICH: February and August have been your in-person meetings, and the other two are conference calls. You do February, May, August, and December.

MR. CACCIATORE: So let me -- unless any other council members have any other suggestions, maybe I'll just coordinate with Dinah and come up with a recommendation for the next meeting on how to handle that. Does that work?

MR. BROCK: Yes, sir.

MR. CACCIATORE: What's our schedule, Dinah,
for -- are we okay as far as everyone's appointments and officers and so forth?

MS. SKRNICH: I think we have a couple that have just recently renewed about a couple months ago, so I'll have to look and see who's up now. Our next meeting -- our next conference call is May the 19th.

MR. CACCIATORE: May the 19th, okay. Is any other business any members of the public or any of the council members like to bring before the council?

MR. ELLIS: Yes, Gary, this is Dean Ellis.

MR. CACCIATORE: Go ahead, Mr. Ellis.

MR. ELLIS: I've had a lot of folks contact me, Reggie, that are confused about who's going to regulate them. I believe I know the answer, but could you address that, because I've just had that question quite a bit.

MR. CACCIATORE: Dean, can you speak up a little? I can't --

MR. ELLIS: I'm sorry. I received questions concerning who is going to regulate the folks here in Florida, and I believe I know the answer to that, but I would like Reggie to maybe share that -- how that regulatory environment's going to
MR. DIXON: Are there -- are they specific license types or just --

MR. ELLIS: No, just wholesale distribution, as it relates to -- because I've had several people who thought that all the regulatory was going to go to the federal law, so I thought maybe you can answer that question.

MR. DIXON: No, it's my understanding with respect to wholesale distributors that there would still be dual-regulation with respect to licensing and compliance with tracking and tracing, and compliance with all of the other requirements that affect the wholesale distributors.

I think the purpose, hopefully, of the tracking and tracing requirements was to try to standardize things for the industry so that they didn't have to have, you know, 50 compliance officers in 50 different states, and world-wide rules and that kind of thing.

So to the extent, hopefully, that the other states were doing similar -- the states -- as Florida, the wholesale distributors that work at least in the -- nationwide, have one set of rules that they have to follow. But I think the
individual states still have jurisdiction to
regulate the activity in their states. And so for
at least Florida, that's what we would be doing.

MR. ELLIS: In Florida, we will have our
inspections from a Florida inspector, not an FDA.

MR. DIXON: Yes.

MR. ELLIS: Thank you.

MR. CACCIATORE: Thank you. Any other
business to be before the council? Okay, hearing
none, I just wanted to say on behalf of the
council, I wanted to thank Mr. Dixon and all the
staff there at the Division for all their efforts.
It's been a busy time, and I think there's been a
lot of work put into both the legislation and the
rules, and I want to thank them for their efforts
to work with the industry to address our concerns.

I'm hoping that the lack of comments from the
council members and from the public indicates that
people are pleased with the rules, and not that
they haven't read them yet, so -- but I think what
you're finding is that the ability of the Division
to work with industry, both on the legislative
issues and the amendments, has been real helpful.
And I also want to thank the legislative affairs
group with DBPR for their efforts as well.
Hearing no other business, I will entertain a motion to adjourn this meeting.

MR. BROCK: So moved.

UNIDENTIFIED SPEAKER: So moved --

MR. CACCIATORE: So moved --

UNIDENTIFIED SPEAKER: -- second.

MR. CACCIATORE: -- and there's a second.

It's been moved and seconded; all in favor of adjournment, signify by saying aye.

(Chorus of ayes.)

MR. CACCIATORE: All opposed? Meeting is adjourned. Thank you, everyone.

(The proceedings were adjourned at 10:39 a.m.)
CERTIFICATE OF REPORTER

I, JEFFREY R. BABCOCK, do hereby certify that I was authorized to and did report the foregoing proceedings, and that the transcript, pages 1 through 52, is a true and correct record of my stenographic notes.

Dated this 14th day of March, 2016 at Tallahassee, Leon County, Florida.

__________________________
JEFFREY BABCOCK
Court Reporter
CHAPTER 2016-230

Committee Substitute for
Committee Substitute for House Bill No. 941

An act relating to the Department of Health; amending s. 20.43, F.S.; renaming the Office of Minority Health within the department; specifying that the office shall be headed by a Senior Health Equity Officer and prescribing his or her duties; amending s. 215.5602, F.S.; revising the reporting requirements for the Biomedical Research Advisory Council under the James and Esther King Biomedical Research program; revising the reporting requirements for certain entities that perform or are associated with cancer research or care; amending s. 381.0034, F.S.; deleting the requirement that applicants making initial application for certain licensure complete certain courses; amending s. 381.7355, F.S.; revising the review criteria for Closing the Gap grant proposals; amending s. 381.82, F.S.; revising the reporting requirements for the Alzheimer’s Disease Research Grant Advisory Board under the Ed and Ethel Moore Alzheimer’s Disease Research Program; providing for the carryforward for a limited period of any unexpended balance of an appropriation for the program; amending s. 381.922, F.S.; providing reporting requirements for the Biomedical Research Advisory Council under the William G. “Bill” Bankhead, Jr., and David Coley Cancer Research Program; amending s. 384.23, F.S.; revising the factors to be considered in designating a condition as a sexually transmissible disease; amending s. 384.27, F.S.; authorizing certain health care practitioners to provide partner therapy under certain conditions; authorizing the department to adopt rules; amending s. 401.27, F.S.; increasing the length of time that an emergency medical technician or paramedic certificate may remain in an inactive status; revising the requirements for reactivating and renewing such a certificate; revising eligibility for certification; deleting a requirement that applicants successfully complete a certification examination within a specified timeframe; amending s. 456.013, F.S.; revising course requirements for renewing a certain license; amending s. 456.024, F.S.; revising the eligibility criteria for a member of the United States Armed Forces, the United States Reserve Forces, or the National Guard and the spouse of an active duty military member to be issued a license to practice as a health care practitioner in this state; creating s. 456.0241, F.S.; providing definitions; providing for issuance of a temporary certificate under certain conditions for certain military health care practitioners; providing for the automatic expiration of the temporary certificate unless renewed; providing for application and renewal fees; requiring the department to adopt rules; creating s. 456.0361, F.S.; requiring the department to establish an electronic continuing education tracking system; prohibiting the department from renewing a license unless the licensee has complied with all continuing education requirements; authorizing the department to adopt rules; amending s. 456.057, F.S.; requiring a person or entity appointed by the board as a custodian of medical records to be approved by

1 CODING: Words stricken are deletions; words underlined are additions.
the department; authorizing the department to contract with a third party to provide custodial services; amending s. 456.0635, F.S.; deleting a provision on applicability relating to the issuance of licenses; amending s. 457.107, F.S.; deleting a provision authorizing the Board of Acupuncture to request certain documentation from applicants; amending s. 458.347, F.S.; deleting a requirement that a physician assistant file a signed affidavit with the department; amending s. 459.022, F.S.; deleting a requirement that a physician assistant file a signed affidavit with the department; amending s. 460.402, F.S.; providing an additional exception to licensure requirements for chiropractic physicians; amending s. 463.007, F.S.; making technical changes; amending s. 464.203, F.S.; revising inservice training requirements for certified nursing assistants; repealing s. 464.2085, F.S., relating to the Council on Certified Nursing Assistants; amending s. 465.027, F.S.; providing an additional exception to pharmacy regulations for manufacturers of dialysis drugs or supplies; amending s. 465.0275, F.S.; revising the amount of emergency prescription refill authorized to be dispensed by a pharmacist; amending s. 465.0276, F.S.; deleting a requirement that the department inspect certain facilities; amending s. 466.0135, F.S.; deleting a requirement that a dentist file a signed affidavit with the department; deleting a provision authorizing the Board of Dentistry to request certain documentation from applicants; amending s. 466.014, F.S.; deleting a requirement that a dental hygienist file a signed affidavit with the department; deleting a provision authorizing the board to request certain documentation from applicants; amending s. 466.032, F.S.; deleting a requirement that a dental laboratory file a signed affidavit with the department; deleting a provision authorizing the department to request certain documentation from applicants; repealing s. 468.1201, F.S., relating to a requirement for instruction on human immunodeficiency virus and acquired immune deficiency syndrome; amending s. 483.901, F.S.; deleting provisions relating to the Advisory Council of Medical Physicists; authorizing the department to issue temporary licenses in certain circumstances; authorizing the department to adopt rules; amending s. 484.047, F.S.; deleting a requirement for a written statement from an applicant in certain circumstances; amending s. 486.102, F.S.; revising accrediting agencies that may approve physical therapy assistant programs for purposes of licensing; amending s. 486.109, F.S.; deleting a provision authorizing the department to conduct a random audit of certain information; amending ss. 499.028, 893.04, and 921.0022, F.S.; conforming provisions and cross-references; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (9) of section 20.43, Florida Statutes, is amended to read:

20.43 Department of Health.—There is created a Department of Health.

CODING: Words stricken are deletions; words underlined are additions.
There is established within the Department of Health the Office of Minority Health and Health Equity, which shall be headed by a Senior Health Equity Officer. The Senior Health Equity Officer shall administer the Closing the Gap grant program established under ss. 381.7351-381.7356 in a manner that maximizes the impact of the grants in achieving health equity. The Senior Health Equity Officer shall evaluate the awarded grants to assess the effectiveness and efficiency of the use of funds and to determine best practices. The Senior Health Equity Officer shall disseminate information on best practices to stakeholders and shall ensure that the assessments inform future grant award decisions.

Section 2. Subsections (10) and (12) of section 215.5602, Florida Statutes, are amended to read:

215.5602 James and Esther King Biomedical Research Program.—

(10) The council shall submit a fiscal-year progress report on the programs under its purview to the Governor, the State Surgeon General, the President of the Senate, and the Speaker of the House of Representatives by December 15. The report must include:

(a) For each A list of research project projects supported by grants or fellowships awarded under the program;

1.(b) A summary list of the research project and results or expected results of the research recipients of program grants or fellowships.

2. The status of the research project, including whether it has concluded or the estimated date of completion.

3. The amount of the grant or fellowship awarded and the estimated or actual cost of the research project.

4.(e) A list of principal investigators under the research project.

5. The title, citation, and summary of findings of a publication publications in a peer-reviewed journal resulting from the peer-reviewed journals involving research supported by grants or fellowships awarded under the program.

6.(d) The source and amount of any federal, state, or local government grants or donations or private grants or donations generated as a result of the research project.

7. The status of a patent, if any, generated from the research project and an economic analysis of the impact of the resulting patent.

8. A list of postsecondary educational institutions involved in the research project, a description of each postsecondary educational institution’s involvement in the research project, and the number of students receiving training or performing research under the research project.
(b) The state ranking and total amount of biomedical research funding currently flowing into the state from the National Institutes of Health.

(e) New grants for biomedical research which were funded based on research supported by grants or fellowships awarded under the program.

(c) Progress towards programmatic goals, particularly in the prevention, diagnosis, treatment, and cure of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease.

(d) Recommendations to further the mission of the programs.

(12) (a) Each Beginning in the 2011-2012 fiscal year and thereafter, $25 million from the revenue deposited into the Health Care Trust Fund pursuant to ss. 210.011(9) and 210.276(7) shall be reserved for research of tobacco-related or cancer-related illnesses. Of the revenue deposited in the Health Care Trust Fund pursuant to this section, $25 million shall be transferred to the Biomedical Research Trust Fund within the Department of Health. Subject to annual appropriations in the General Appropriations Act, $5 million shall be appropriated to the James and Esther King Biomedical Research Program, and $5 million shall be appropriated to the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program created under s. 381.922.

(b) Beginning July 1, 2014, An entity that performs or is associated with cancer research or care that receives a specific appropriation for biomedical research, research-related functions, operations or other supportive functions, or expansion of operations in the General Appropriations Act without statutory reporting requirements for the receipt of those funds, must submit an annual fiscal-year progress report to the President of the Senate and the Speaker of the House of Representatives by December 15. The report must:

1. Describe the general use of the funds.

2. Summarize the research, if any, funded by the appropriation and provide the:

   a. Status of the research, including whether the research has concluded.

   b. Results or expected results of the research.

   c. Names of principal investigators performing the research.

   d. Title, citation, and summary of findings of a publication in a peer-reviewed journal resulting from the research.

   e. Status of a patent, if any, generated from the research and an economic analysis of the impact of the resulting patent.
List of postsecondary educational institutions involved in the research, a description of each postsecondary educational institution’s involvement in the research, and the number of students receiving training or performing research.

3. Describe any fixed capital outlay project funded by the appropriation, the need for the project, how the project will be utilized, and the timeline for and status of the project, if applicable.

4. Identify any federal, state, or local government grants or donations or private grants or donations generated as a result of the appropriation or activities funded by the appropriation, if applicable and traceable.

Section 3. Subsection (3) of section 381.0034, Florida Statutes, is amended to read:

381.0034 Requirement for instruction on HIV and AIDS.—

(3) The department shall require, as a condition of granting a license under chapter 467 or part III of chapter 483 the chapters specified in subsection (1), that an applicant making initial application for licensure complete an educational course acceptable to the department on human immunodeficiency virus and acquired immune deficiency syndrome. Upon submission of an affidavit showing good cause, an applicant who has not taken a course at the time of licensure shall, upon an affidavit showing good cause, be allowed 6 months to complete this requirement.

Section 4. Paragraph (a) of subsection (2) of section 381.7355, Florida Statutes, is amended, and paragraph (i) is added to subsection (3) of that section, to read:

381.7355 Project requirements; review criteria.—

(2) A proposal must include each of the following elements:

(a) The purpose and objectives of the proposal, including identification of the particular racial or ethnic disparity the project will address. The proposal must address one or more of the following priority areas:

1. Decreasing racial and ethnic disparities in maternal and infant mortality rates.

2. Decreasing racial and ethnic disparities in morbidity and mortality rates relating to cancer.

3. Decreasing racial and ethnic disparities in morbidity and mortality rates relating to HIV/AIDS.

4. Decreasing racial and ethnic disparities in morbidity and mortality rates relating to cardiovascular disease.

CODING: Words stricken are deletions; words underlined are additions.
5. Decreasing racial and ethnic disparities in morbidity and mortality rates relating to diabetes.

6. Increasing adult and child immunization rates in certain racial and ethnic populations.

7. Decreasing racial and ethnic disparities in oral health care.

8. Decreasing racial and ethnic disparities in morbidity and mortality rates relating to sickle cell disease.

9. Improve neighborhood social determinants of health, such as transportation, safety, and food access, as outlined by the Centers for Disease Control and Prevention’s “Tools for Putting Social Determinants of Health into Action.”

(3) Priority shall be given to proposals that:

(i) Incorporate policy approaches to achieve sustainable long-term improvement.

Section 5. Subsection (4) of section 381.82, Florida Statutes, is amended, and subsection (8) is added to that section, to read:

381.82 Ed and Ethel Moore Alzheimer’s Disease Research Program.—

(4) The board shall submit a fiscal-year progress report on the programs under its purview annually to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the State Surgeon General by February 15. The report must include:

(a) For each A list of research project projects supported by grants or fellowships awarded under the program:

1. A summary list of the research project and results or expected results of the research recipients of program grants or fellowships.

2. The status of the research project, including whether it has concluded or the estimated date of completion.

3. The amount of the grant or fellowship awarded and the estimated or actual cost of the research project.

4. A list of principal investigators under the research project.

5. The title, citation, and summary of findings of a publication publications in a peer-reviewed journal resulting from the journals involving research supported by grants or fellowships awarded under the program.

6. The source and amount of any federal, state, or local government grants or donations or private grants or donations generated as a result of the research project.

CODING: Words stricken are deletions; words underlined are additions.
7. The status of a patent, if any, generated from the research project and an economic analysis of the impact of the resulting patent.

8. A list of postsecondary educational institutions involved in the research project, a description of each postsecondary educational institution’s involvement in the research project, and the number of students receiving training or performing research under the research project.

(b)(d) The state ranking and total amount of Alzheimer’s disease research funding currently flowing into the state from the National Institutes of Health.

(e) New grants for Alzheimer’s disease research which were funded based on research supported by grants or fellowships awarded under the program.

(c)(f) Progress toward programmatic goals, particularly in the prevention, diagnosis, treatment, and cure of Alzheimer’s disease.

(d)(g) Recommendations to further the mission of the program.

(8) Notwithstanding s. 216.301 and pursuant to s. 216.351, the balance of any appropriation from the General Revenue Fund for the Ed and Ethel Moore Alzheimer’s Disease Research Program which is not disbursed but which is obligated pursuant to contract or committed to be expended by June 30 of the fiscal year in which the funds are appropriated may be carried forward for up to 5 years after the effective date of the original appropriation.

Section 6. Subsection (6) is added to section 381.922, Florida Statutes, to read:

381.922 William G. “Bill” Bankhead, Jr., and David Coley Cancer Research Program.—

(6) The Biomedical Research Advisory Council shall submit a report relating to grants awarded under the program to the Governor, the President of the Senate, and the Speaker of the House of Representatives by December 15 each year. The report must include:

(a) For each research project supported by grants or fellowships awarded under the program:

1. A summary of the research project and results or expected results of the research.

2. The status of the research project, including whether it has concluded or the estimated date of completion.

3. The amount of the grant or fellowship awarded and the estimated or actual cost of the research project.

4. A list of principal investigators under the research project.
5. The title, citation, and summary of findings of a publication in a peer-reviewed journal resulting from the research.

6. The source and amount of any federal, state, or local government grants or donations or private grants or donations generated as a result of the research project.

7. The status of a patent, if any, generated from the research project and an economic analysis of the impact of the resulting patent.

8. A list of postsecondary educational institutions involved in the research project, a description of each postsecondary educational institution’s involvement in the research project, and the number of students receiving training or performing research under the research project.

(b) The state ranking and total amount of cancer research funding currently flowing into the state from the National Institutes of Health.

(c) Progress toward programmatic goals, particularly in the prevention, diagnosis, treatment, and cure of cancer.

(d) Recommendations to further the mission of the program.

Section 7. Subsection (3) of section 384.23, Florida Statutes, is amended to read:

384.23 Definitions.—

(3) “Sexually transmissible disease” means a bacterial, viral, fungal, or parasitic disease; determined by rule of the department to be sexually transmissible, to be a threat to the public health and welfare, and to be a disease for which a legitimate public interest will be served by providing for prevention, elimination, control, regulation and treatment. The department must, by rule, determine in considering which diseases are to be designated as sexually transmissible diseases, the department shall consider such diseases as chancroid, gonorrhea, granuloma inguinale, lymphogranuloma venereum, genital herpes simplex, chlamydia, nongonococcal urethritis (NGU), pelvic inflammatory disease (PID)/acute salpingitis, syphilis, and human immune deficiency virus infection for designation, and shall consider the recommendations and classifications of the Centers for Disease Control and Prevention and other nationally recognized medical authorities in that determination. Not all diseases that are sexually transmissible need be designated for the purposes of this act.

Section 8. Subsection (7) is added to section 384.27, Florida Statutes, to read:

384.27 Physical examination and treatment.—

CODING: Words stricken are deletions; words underlined are additions.
(a) A health care practitioner licensed under chapter 458 or chapter 459 or certified under s. 464.012 may provide expedited partner therapy if the following requirements are met:

1. The patient has a laboratory-confirmed or suspected clinical diagnosis of a sexually transmissible disease.

2. The patient indicates that he or she has a partner with whom he or she engaged in sexual activity before the diagnosis of the sexually transmissible disease.

3. The patient indicates that his or her partner is unable or unlikely to seek clinical services in a timely manner.

(b) A pharmacist licensed under chapter 465 may dispense medication to a person diagnosed with a sexually transmissible disease pursuant to a prescription for the purpose of treating that person’s partner, regardless of whether the person’s partner has been personally examined by the prescribing health care practitioner.

(c) A pharmacist or health care practitioner must check for potential allergic reactions, in accordance with the prevailing professional standard of care, before dispensing a prescription or providing a medication under this subsection.

(d) The department may adopt rules to implement this subsection.

Section 9. Subsections (8) and (12) of section 401.27, Florida Statutes, are amended to read:

401.27 Personnel; standards and certification.—

(8) Each emergency medical technician certificate and each paramedic certificate will expire automatically and may be renewed if the holder meets the qualifications for renewal as established by the department. A certificate that is not renewed at the end of the 2-year period will automatically revert to an inactive status for a period not to exceed two renewal periods 180 days. Such certificate may be reactivated and renewed within the two renewal periods 180 days if the certificateholder meets all other qualifications for renewal, including continuing education requirements, and pays a $25 late fee. The certificateholder also must pass the certification examination to reactivate the certificate during the second of the two renewal periods. Reactivation shall be in a manner and on forms prescribed by department rule.

(12) An applicant for certification as an emergency medical technician or paramedic who is trained outside the state, or trained in the military, must provide proof of a current, nationally recognized emergency medical technician or paramedic certification or registration that is recognized by the department and based upon successful completion of a training program approved by the department as being equivalent to the most recent EMT-
Basic or EMT-Paramedic National Standard Curriculum or the National EMS Education Standards of the United States Department of Transportation and hold a current certificate of successful course completion in cardiopulmonary resuscitation (CPR) or advanced cardiac life support for emergency medical technicians or paramedics, respectively, to be eligible for the certification examination. The applicant must successfully complete the certification examination within 2 years after the date of the receipt of his or her application by the department. After 2 years, the applicant must submit a new application, meet all eligibility requirements, and submit all fees to reestablish eligibility to take the certification examination.

Section 10. Subsection (7) of section 456.013, Florida Statutes, is amended to read:

456.013 Department; general licensing provisions.—

(7) The boards, or the department when there is no board, shall require the completion of a 2-hour course relating to prevention of medical errors as part of the biennial licensure and renewal process. The 2-hour course counts toward the total number of continuing education hours required for the profession. The course must be approved by the board or department, as appropriate, and must include a study of root-cause analysis, error reduction and prevention, and patient safety. In addition, the course approved by the Board of Medicine and the Board of Osteopathic Medicine must include information relating to the five most misdiagnosed conditions during the previous biennium, as determined by the board. If the course is being offered by a facility licensed pursuant to chapter 395 for its employees, the board may approve up to 1 hour of the 2-hour course to be specifically related to error reduction and prevention methods used in that facility.

Section 11. Subsection (3) of section 456.024, Florida Statutes, is amended to read:

456.024 Members of Armed Forces in good standing with administrative boards or the department; spouses; licensure.—

(3)(a) A person is eligible for licensure as a health care practitioner in this state if he or she:

1. who Serves or has served as a health care practitioner in the United States Armed Forces, the United States Reserve Forces, or the National Guard;

2. or a person who Serves or has served on active duty with the United States Armed Forces as a health care practitioner in the United States Public Health Service; or

3. Is a health care practitioner, other than a dentist, in another state, the District of Columbia, or a possession or territory of the United States and is

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the spouse of a person serving on active duty with the United States Armed Forces is eligible for licensure in this state.

The department shall develop an application form, and each board, or the department if there is no board, shall waive the application fee, licensure fee, and unlicensed activity fee for such applicants. For purposes of this subsection, “health care practitioner” means a health care practitioner as defined in s. 456.001 and a person licensed under part III of chapter 401 or part IV of chapter 468.

(b) The board, or the department if there is no board, shall issue a license to practice in this state to a person who:

1. Submits a complete application.

2. If he or she is a member of the United States Armed Forces, the United States Reserve Forces, or the National Guard, submits proof that he or she has received an honorable discharge within 6 months before, or will receive an honorable discharge within 6 months after, the date of submission of the application.

3.a. Holds an active, unencumbered license issued by another state, the District of Columbia, or a possession or territory of the United States and who has not had disciplinary action taken against him or her in the 5 years preceding the date of submission of the application; or

b. Is a military health care practitioner in a profession for which licensure in a state or jurisdiction is not required to practice in the United States Armed Forces, if he or she submits to the department evidence of military training or experience substantially equivalent to the requirements for licensure in this state in that profession and evidence that he or she has obtained a passing score on the appropriate examination of a national or regional standards organization if required for licensure in this state; or

c. Is the spouse of a person serving on active duty in the United States Armed Forces and is a health care practitioner in a profession, excluding dentistry, for which licensure in another state or jurisdiction is not required, if he or she submits to the department evidence of training or experience substantially equivalent to the requirements for licensure in this state in that profession and evidence that he or she has obtained a passing score on the appropriate examination of a national or regional standards organization if required for licensure in this state.

4. Attestst that he or she is not, at the time of submission of the application, the subject of a disciplinary proceeding in a jurisdiction in which he or she holds a license or by the United States Department of Defense for reasons related to the practice of the profession for which he or she is applying.

5. Actively practiced the profession for which he or she is applying for the 3 years preceding the date of submission of the application.

CODING: Words stricken are deletions; words underlined are additions.
6. Submits a set of fingerprints for a background screening pursuant to s. 456.0135, if required for the profession for which he or she is applying. The department shall verify information submitted by the applicant under this subsection using the National Practitioner Data Bank.

(c) Each applicant who meets the requirements of this subsection shall be licensed with all rights and responsibilities as defined by law. The applicable board, or the department if there is no board, may deny an application if the applicant has been convicted of or pled guilty or nolo contendere to, regardless of adjudication, any felony or misdemeanor related to the practice of a health care profession regulated by this state.

(d) An applicant for initial licensure under this subsection must submit the information required by ss. 456.039(1) and 456.0391(1) no later than 1 year after the license is issued.

Section 12. Section 456.0241, Florida Statutes, is created to read:

456.0241 Temporary certificate for active duty military health care practitioners.—

(1) As used in this section, the term:

(a) “Military health care practitioner” means:

1. A person practicing as a health care practitioner as defined in s. 456.001, as a person licensed under part III of chapter 401, or as a person licensed under part IV of chapter 468 who is serving on active duty in the United States Armed Forces, the United States Reserve Forces, or the National Guard; or

2. A person who is serving on active duty in the United States Armed Forces and serving in the United States Public Health Service.

(b) “Military platform” means a military training agreement with a nonmilitary health care provider that is designed to develop and support medical, surgical, or other health care treatment opportunities in a nonmilitary health care provider setting to authorize a military health care practitioner to develop and maintain the technical proficiency necessary to meet the present and future health care needs of the United States Armed Forces. Such agreements may include Training Affiliation Agreements and External Resource Sharing Agreements.

(2) The department may issue a temporary certificate to an active duty military health care practitioner to practice in a regulated profession in this state if the applicant:

(a) Submits proof that he or she will be practicing pursuant to a military platform.

CODING: Words stricken are deletions; words underlined are additions.
(b) Submits a complete application and a nonrefundable application fee.

(c) Holds an active, unencumbered license to practice as a health care professional issued by another state, the District of Columbia, or a possession or territory of the United States or is a military health care practitioner in a profession for which licensure in a state or jurisdiction is not required for practice in the United States Armed Forces and provides evidence of military training and experience substantially equivalent to the requirements for licensure in this state in that profession.

(d) Attests that he or she is not, at the time of submission of the application, the subject of a disciplinary proceeding in a jurisdiction in which he or she holds a license or by the United States Department of Defense for reasons related to the practice of the profession for which he or she is applying.

(e) Has been determined to be competent in the profession for which he or she is applying.

(f) Submits a set of fingerprints for a background screening pursuant to s. 456.0135, if required for the profession for which he or she is applying.

The department shall verify information submitted by the applicant under this subsection using the National Practitioner Data Bank.

(3) A temporary certificate issued under this section expires 6 months after issuance but may be renewed upon proof of continuing military orders for active duty assignment in this state and evidence that the military health care practitioner continues to be a military platform participant.

(4) A military health care practitioner applying for a temporary certificate under this section is exempt from ss. 456.039-456.046. All other provisions of this chapter apply to such military health care practitioner.

(5) An applicant for a temporary certificate under this section is deemed ineligible if he or she:

(a) Has been convicted of or pled guilty or nolo contendere to, regardless of adjudication, any felony or misdemeanor related to the practice of a health care profession;

(b) Has had a health care provider license revoked or suspended in another state, the District of Columbia, or a possession or territory of the United States;

(c) Has failed to obtain a passing score on the Florida examination required to receive a license to practice the profession for which he or she is applying; or
(d) Is under investigation in another jurisdiction for an act that would constitute a violation of the applicable licensing chapter or this chapter until the investigation is complete and all charges against him or her are disposed of by dismissal, nolle prosequi, or acquittal.

(6) The department shall, by rule, set an application fee not to exceed $50 and a renewal fee not to exceed $50.

(7) Application shall be made on a form prescribed and furnished by the department.

(8) The department shall adopt rules to implement this section.

Section 13. Section 456.0361, Florida Statutes, is created to read:

456.0361 Compliance with continuing education requirements.—

(1) The department shall establish an electronic continuing education tracking system to monitor licensee compliance with applicable continuing education requirements and to determine whether a licensee is in full compliance with the requirements at the time of his or her application for license renewal. The tracking system shall be integrated into the department’s licensure and renewal process.

(2) The department may not renew a license until the licensee complies with all applicable continuing education requirements. This subsection does not prohibit the department or the boards from imposing additional penalties under the applicable professional practice act or applicable rules for failure to comply with continuing education requirements.

(3) The department may adopt rules to implement this section.

Section 14. Subsection (20) of section 456.057, Florida Statutes, is amended to read:

456.057 Ownership and control of patient records; report or copies of records to be furnished; disclosure of information.—

(20) The board with department approval, or the department when there is no board, may temporarily or permanently appoint a person or entity as a custodian of medical records in the event of the death of a practitioner, the mental or physical incapacitation of a practitioner, or the abandonment of medical records by a practitioner. Such The custodian appointed shall comply with all provisions of this section. The department may contract with a third party to provide these services under the confidentiality and disclosure requirements of this section, including the release of patient records.

Section 15. Subsection (2) of section 456.0635, Florida Statutes, is amended to read:

CODING: Words stricken are deletions; words underlined are additions.
(2) Each board within the jurisdiction of the department, or the department if there is no board, shall refuse to admit a candidate to any examination and refuse to issue a license, certificate, or registration to any applicant if the candidate or applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant:

(a) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, unless the candidate or applicant has successfully completed a drug court program for that felony and provides proof that the plea has been withdrawn or the charges have been dismissed. Any such conviction or plea shall exclude the applicant or candidate from licensure, examination, certification, or registration unless the sentence and any subsequent period of probation for such conviction or plea ended:

1. For felonies of the first or second degree, more than 15 years before the date of application.

2. For felonies of the third degree, more than 10 years before the date of application, except for felonies of the third degree under s. 893.13(6)(a).

3. For felonies of the third degree under s. 893.13(6)(a), more than 5 years before the date of application;

(b) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970, or 42 U.S.C. ss. 1395-1396, unless the sentence and any subsequent period of probation for such conviction or plea ended more than 15 years before the date of the application;

(c) Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the candidate or applicant has been in good standing with the Florida Medicaid program for the most recent 5 years;

(d) Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the candidate or applicant has been in good standing with a state Medicaid program for the most recent 5 years and the termination occurred at least 20 years before the date of the application; or

(e) Is currently listed on the United States Department of Health and Human Services Office of Inspector General’s List of Excluded Individuals and Entities.

This subsection does not apply to candidates or applicants for initial licensure or certification who were enrolled in an educational or training program on or before July 1, 2009, which was recognized by a board or, if
there is no board, recognized by the department, and who applied for licensure after July 1, 2012.

Section 16. Subsection (3) of section 457.107, Florida Statutes, is amended to read:

457.107 Renewal of licenses; continuing education.—

(3) The board shall by rule prescribe continuing education requirements of up to, not to exceed 30 hours biennially, as a condition for renewal of a license. All education programs that contribute to the advancement, extension, or enhancement of professional skills and knowledge related to the practice of acupuncture, whether conducted by a nonprofit or profitmaking entity, are eligible for approval. The continuing professional education requirements must be in acupuncture or oriental medicine subjects, including, but not limited to, anatomy, biological sciences, adjunctive therapies, sanitation and sterilization, emergency protocols, and diseases. The board may have the authority to set a fee of up to, not to exceed $100, for each continuing education provider. The licensee shall retain in his or her records the certificates of completion of continuing professional education requirements to prove compliance with this subsection. The board may request such documentation without cause from all national and state acupuncture and oriental medicine organizations and acupuncture and oriental medicine schools are approved to provide continuing professional education in accordance with this subsection.

Section 17. Paragraph (e) of subsection (4) of section 458.347, Florida Statutes, is amended to read:

458.347 Physician assistants.—

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(e) A supervisory physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervisory physician’s practice unless such medication is listed on the formulary created pursuant to paragraph (f). A fully licensed physician assistant may only prescribe or dispense such medication under the following circumstances:

1. A physician assistant must clearly identify to the patient that he or she is a physician assistant and. Furthermore, the physician assistant must inform the patient that the patient has the right to see the physician before a prescription is being prescribed or dispensed by the physician assistant.

2. The supervisory physician must notify the department of his or her intent to delegate, on a department-approved form, before delegating such authority and notify the department of any change in prescriptive privileges of the physician assistant. Authority to dispense may be delegated only by a
supervising physician who is registered as a dispensing practitioner in compliance with s. 465.0276.

3. The physician assistant must complete file with the department a signed affidavit that he or she has completed a minimum of 10 continuing medical education hours in the specialty practice in which the physician assistant has prescriptive privileges with each licensure renewal application.

4. The department may issue a prescriber number to the physician assistant granting authority for the prescribing of medicinal drugs authorized within this paragraph upon completion of the foregoing requirements of this paragraph. The physician assistant is not be required to independently register pursuant to s. 465.0276.

5. The prescription must be written in a form that complies with chapter 499 and, in addition to the supervisory physician’s name, address, and telephone number, must contain, in addition to the supervisory physician’s name, address, and telephone number, the physician assistant’s prescriber number. Unless it is a drug or drug sample dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under chapter 465 and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465. The inclusion appearance of the prescriber number creates a presumption that the physician assistant is authorized to prescribe the medicinal drug and the prescription is valid.

6. The physician assistant must note the prescription or dispensing of medication in the appropriate medical record.

Section 18. Paragraph (e) of subsection (4) of section 459.022, Florida Statutes, is amended to read:

459.022 Physician assistants.—

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(e) A supervisory physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervisory physician’s practice unless such medication is listed on the formulary created pursuant to s. 458.347. A fully licensed physician assistant may only prescribe or dispense such medication under the following circumstances:

1. A physician assistant must clearly identify to the patient that she or he is a physician assistant and. Furthermore, the physician assistant must inform the patient that the patient has the right to see the physician before a prior to any prescription is being prescribed or dispensed by the physician assistant.

2. The supervisory physician must notify the department of her or his intent to delegate, on a department-approved form, before delegating such
authority and notify the department of any change in prescriptive privileges of the physician assistant. Authority to dispense may be delegated only by a supervisory physician who is registered as a dispensing practitioner in compliance with s. 465.0276.

3. The physician assistant must complete file with the department a signed affidavit that she or he has completed a minimum of 10 continuing medical education hours in the specialty practice in which the physician assistant has prescriptive privileges with each licensure renewal application.

4. The department may issue a prescriber number to the physician assistant granting authority for the prescribing of medicinal drugs authorized within this paragraph upon completion of the foregoing requirements of this paragraph. The physician assistant is shall not be required to independently register pursuant to s. 465.0276.

5. The prescription must be written in a form that complies with chapter 499 and, in addition to the supervisory physician's name, address, and telephone number, must contain, in addition to the supervisory physician's name, address, and telephone number, the physician assistant's prescriber number. Unless it is a drug or drug sample dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under chapter 465, and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465. The inclusion appearance of the prescriber number creates a presumption that the physician assistant is authorized to prescribe the medicinal drug and the prescription is valid.

6. The physician assistant must note the prescription or dispensing of medication in the appropriate medical record.

Section 19. Subsection (7) is added to section 460.402, Florida Statutes, to read:

460.402 Exceptions.—The provisions of this chapter shall not apply to:

(7) A chiropractic physician who holds an active license in another state, the District of Columbia, or a possession or territory of the United States and is performing chiropractic procedures or demonstrating equipment or supplies for educational purposes at a board-approved continuing education program.

Section 20. Subsection (3) of section 463.007, Florida Statutes, is amended to read:

463.007 Renewal of license; continuing education.—

(3) As a condition of license renewal, a licensee must Unless otherwise provided by law, the board shall require licensees to periodically demonstrate his or her their professional competence, as a condition of renewal of a license, by completing up to 30 hours of continuing education during the 2-
year period preceding license renewal. For certified optometrists, the 30-hour continuing education requirement includes shall include 6 or more hours of approved transcript-quality coursework in ocular and systemic pharmacology and the diagnosis, treatment, and management of ocular and systemic conditions and diseases during the 2-year period preceding application for license renewal.

Section 21. Subsection (7) of section 464.203, Florida Statutes, is amended to read:

464.203 Certified nursing assistants; certification requirement.—

(7) A certified nursing assistant shall complete 24 12 hours of inservice training during each biennium calendar year. The certified nursing assistant shall maintain be responsible for maintaining documentation demonstrating compliance with these provisions. The Council on Certified Nursing Assistants, in accordance with s. 464.2085(2)(b), shall propose rules to implement this subsection.

Section 22. Section 464.2085, Florida Statutes, is repealed.

Section 23. Section 465.027, Florida Statutes, is amended to read:

465.027 Exceptions.—

(1) This chapter shall not be construed to prohibit the sale of home remedies or preparations commonly known as patents or proprietary preparations, when such are sold only in original or unbroken packages, nor shall this chapter be construed to prevent businesses from engaging in the sale of sundries or patents or proprietary preparations.

(2) This chapter shall not apply to a manufacturer, or its agent, holding an active permit as a manufacturer under chapter 499 and engaged solely in the manufacture or distribution of dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure, if the dialysate, drugs, or devices are:

(a) Approved or cleared by the United States Food and Drug Administration; and

(b) Delivered in the original, sealed packaging after receipt of a physician’s order to dispense to:

1. A patient with chronic kidney failure, or the patient’s designee, for the patient’s self-administration of the dialysis therapy; or

2. A health care practitioner or an institution for administration or delivery of the dialysis therapy to a patient with chronic kidney failure.

Section 24. Section 465.0275, Florida Statutes, is amended to read:

465.0275 Emergency prescription refill.—

CODING: Words stricken are deletions; words underlined are additions.
(1) In the event a pharmacist receives a request for a prescription refill and the pharmacist is unable to readily obtain refill authorization from the prescriber, the pharmacist may dispense:

(a) A one-time emergency refill of up to a 72-hour supply of the prescribed medication; or

(b) A one-time emergency refill of one vial of insulin to treat diabetes mellitus.

(2) If the Governor issues, with the exception of those areas or counties included in an emergency order or proclamation of a state of emergency declared by the Governor, in which the executive order may authorize the pharmacist may to dispense up to a 30-day supply in the areas or counties affected by the order or proclamation, provided providing that:

(a) The prescription is not for a medicinal drug listed in Schedule II appearing in chapter 893.

(b) The medication is essential to the maintenance of life or to the continuation of therapy in a chronic condition.

(c) In the pharmacist’s professional judgment, the interruption of therapy might reasonably produce undesirable health consequences or may cause physical or mental discomfort.

(d) The dispensing pharmacist creates a written order containing all of the prescription information required by this chapter and chapters 499 and 893 and signs that order.

(e) The dispensing pharmacist notifies the prescriber of the emergency dispensing within a reasonable time after such dispensing.

Section 25. Paragraph (b) of subsection (1) and subsection (3) of section 465.0276, Florida Statutes, are amended to read:

465.0276 Dispensing practitioner.—

(1)

(b) A practitioner registered under this section may not dispense a controlled substance listed in Schedule II or Schedule III as provided in s. 893.03. This paragraph does not apply to:

1. The dispensing of complimentary packages of medicinal drugs which are labeled as a drug sample or complimentary drug as defined in s. 499.028 to the practitioner’s own patients in the regular course of her or his practice without the payment of a fee or remuneration of any kind, whether direct or indirect, as provided in subsection (4) (5).

2. The dispensing of controlled substances in the health care system of the Department of Corrections.

CODING: Words stricken are deletions; words underlined are additions.
3. The dispensing of a controlled substance listed in Schedule II or Schedule III in connection with the performance of a surgical procedure. The amount dispensed pursuant to the subparagraph may not exceed a 14-day supply. This exception does not allow for the dispensing of a controlled substance listed in Schedule II or Schedule III more than 14 days after the performance of the surgical procedure. For purposes of this subparagraph, the term “surgical procedure” means any procedure in any setting which involves, or reasonably should involve:

   a. Perioperative medication and sedation that allows the patient to tolerate unpleasant procedures while maintaining adequate cardiorespiratory function and the ability to respond purposefully to verbal or tactile stimulation and makes intra- and postoperative monitoring necessary; or

   b. The use of general anesthesia or major conduction anesthesia and preoperative sedation.

4. The dispensing of a controlled substance listed in Schedule II or Schedule III pursuant to an approved clinical trial. For purposes of this subparagraph, the term “approved clinical trial” means a clinical research study or clinical investigation that, in whole or in part, is state or federally funded or is conducted under an investigational new drug application that is reviewed by the United States Food and Drug Administration.

5. The dispensing of methadone in a facility licensed under s. 397.427 where medication-assisted treatment for opiate addiction is provided.

6. The dispensing of a controlled substance listed in Schedule II or Schedule III to a patient of a facility licensed under part IV of chapter 400.

   (3) The department shall inspect any facility where a practitioner dispenses medicinal drugs pursuant to subsection (2) in the same manner and with the same frequency as it inspects pharmacies for the purpose of determining whether the practitioner is in compliance with all statutes and rules applicable to her or his dispensing practice.

Section 26. Subsection (3) of section 466.0135, Florida Statutes, is amended to read:

466.0135 Continuing education; dentists.—

   (3) A In applying for license renewal, the dentist shall complete submit a sworn affidavit, on a form acceptable to the department, attesting that she or he has completed the required continuing education as provided required in this section and in accordance with the guidelines and provisions of this section and listing the date, location, sponsor, subject matter, and hours of completed continuing education courses. The applicant shall retain in her or his records any such receipts, vouchers, or certificates as may be necessary to document completion of such the continuing education courses listed in accordance with this subsection. With cause, the board may request
such documentation by the applicant, and the board may request such
documentation from applicants selected at random without cause.

Section 27. Section 466.014, Florida Statutes, is amended to read:

466.014 Continuing education; dental hygienists.—In addition to the
other requirements for relicensure for dental hygienists set out in this
chapter, the board shall require each licensed dental hygienist to
complete at least not less than 24 hours but not or more than 36 hours of
continuing professional education in dental subjects, biennially, in programs
prescribed or approved by the board or in equivalent programs of continuing
education. Programs of continuing education approved by the board shall be
programs of learning which, in the opinion of the board, contribute directly
to the dental education of the dental hygienist. The board shall adopt rules
and guidelines to administer and enforce the provisions of this section. In
applying for license renewal, The dental hygienist shall submit a sworn
affidavit, on a form acceptable to the department, attesting that she or he
has completed the continuing education required in this section in
accordance with the guidelines and provisions of this section and listing
the date, location, sponsor, subject matter, and hours of completed
continuing education courses. The applicant shall retain in her or his
records any such receipts, vouchers, or certificates as may be necessary to
document completion of such the continuing education courses listed in
accordance with this section. With cause, the board may request such
documentation by the applicant, and the board may request such docu-
dmentation from applicants selected at random without cause. Compliance
with the continuing education requirements is shall be mandatory for
issuance of the renewal certificate. The board may shall have the authority
to excuse licensees, as a group or as individuals, from all or part of the
continuing education educational requirements if, or any part thereof, in the
event an unusual circumstance, emergency, or hardship has prevented
compliance with this section.

Section 28. Subsection (5) of section 466.032, Florida Statutes, is
amended to read:

466.032 Registration.—

(5) A The dental laboratory owner or at least one employee of any dental
laboratory renewing registration on or after July 1, 2010, shall complete 18
hours of continuing education biennially. Programs of continuing education
must shall be programs of learning that contribute directly to the education
of the dental technician and may include, but are not limited to, attendance
at lectures, study clubs, college courses, or scientific sessions of conventions
and research.

(a) The aim of continuing education for dental technicians is to improve
dental health care delivery to the public as such is impacted through the
design, manufacture, and use of artificial human oral prosthetics and
related restorative appliances.

CODING: Words stricken are deletions; words underlined are additions.
(b) Continuing education courses shall address one or more of the following areas of professional development, including, but not limited to:

1. Laboratory and technological subjects, including, but not limited to, laboratory techniques and procedures, materials, and equipment; and

2. Subjects pertinent to oral health, infection control, and safety.

(c) Programs that meet the general requirements of continuing education may be developed and offered to dental technicians by the Florida Dental Laboratory Association and the Florida Dental Association. Other organizations, schools, or agencies may also be approved to develop and offer continuing education in accordance with specific criteria established by the department.

(d) Any dental laboratory renewing a registration on or after July 1, 2010, shall submit a sworn affidavit, on a form approved by the department, attesting that either the dental laboratory owner or one dental technician employed by the registered dental laboratory has completed the continuing education required in this subsection in accordance with the guidelines and provisions of this subsection and listing the date, location, sponsor, subject matter, and hours of completed continuing education courses. The dental laboratory shall retain in its records such receipts, vouchers, or certificates as may be necessary to document completion of the continuing education courses listed in accordance with this subsection. With cause, the department may request that the documentation be provided by the applicant. The department may also request the documentation from applicants selected at random without cause.

(d)(e)1. This subsection does not apply to a dental laboratory that is physically located within a dental practice operated by a dentist licensed under this chapter.

2. A dental laboratory in another state or country which provides service to a dentist licensed under this chapter is not required to register with the state and may continue to provide services to such dentist with a proper prescription. However, a dental laboratory in another state or country, however, may voluntarily comply with this subsection.

Section 29. Section 468.1201, Florida Statutes, is repealed.

Section 30. Paragraph (a) of subsection (3), subsections (4) and (5), paragraphs (a) and (e) of present subsection (6), and present subsection (7) of section 483.901, Florida Statutes, are amended, and paragraph (k) is added to present subsection (6) of that section, to read:

483.901 Medical physicists; definitions; licensure.—

(3) DEFINITIONS.—As used in this section, the term:

CODING: Words stricken are deletions; words underlined are additions.
(a) “Council” means the Advisory Council of Medical Physicists in the Department of Health.

(4) COUNCIL.—The Advisory Council of Medical Physicists is created in the Department of Health to advise the department in regulating the practice of medical physics in this state.

(a) The council shall be composed of nine members appointed by the State Surgeon General as follows:

1. A licensed medical physicist who specializes in diagnostic radiological physics.


3. A licensed medical physicist who specializes in medical nuclear radiological physics.

4. A physician who is board certified by the American Board of Radiology or its equivalent.

5. A physician who is board certified by the American Osteopathic Board of Radiology or its equivalent.

6. A chiropractic physician who practices radiology.

7. Three consumer members who are not, and have never been, licensed as a medical physicist or licensed in any closely related profession.

(b) The State Surgeon General shall appoint the medical physicist members of the council from a list of candidates who are licensed to practice medical physics.

(c) The State Surgeon General shall appoint the physician members of the council from a list of candidates who are licensed to practice medicine in this state and are board certified in diagnostic radiology, therapeutic radiology, or radiation oncology.

(d) The State Surgeon General shall appoint the public members of the council.

(e) As the term of each member expires, the State Surgeon General shall appoint the successor for a term of 4 years. A member shall serve until the member’s successor is appointed, unless physically unable to do so.

(f) An individual is ineligible to serve more than two full consecutive 4-year terms.

(g) If a vacancy on the council occurs, the State Surgeon General shall appoint a member to serve for a 4-year term.

CODING: Words stricken are deletions; words underlined are additions.
(h) A council member must be a United States citizen and must have been a resident of this state for 2 consecutive years immediately before being appointed.

1. A member of the council who is a medical physicist must have practiced for at least 6 years before being appointed or be board certified for the specialty in which the member practices.

2. A member of the council who is a physician must be licensed to practice medicine in this state and must have practiced diagnostic radiology or radiation oncology in this state for at least 2 years before being appointed.

3. The public members of the council must not have a financial interest in any endeavor related to the practice of medical physics.

(i) A council member may be removed from the council if the member:

1. Did not have the required qualifications at the time of appointment;

2. Does not maintain the required qualifications while serving on the council; or

3. Fails to attend the regularly scheduled council meetings in a calendar year as required by s. 456.011.

(j) Members of the council may not receive compensation for their services; however, they are entitled to reimbursement, from funds deposited in the Medical Quality Assurance Trust Fund, for necessary travel expenses as specified in s. 112.061 for each day they engage in the business of the council.

(k) At the first regularly scheduled meeting of each calendar year, the council shall elect a presiding officer and an assistant presiding officer from among its members. The council shall meet at least once each year and at other times in accordance with department requirements.

(l) The department shall provide administrative support to the council for all licensing activities.

(m) The council may conduct its meetings electronically.

(5) POWERS OF COUNCIL.—The council shall:

(a) Recommend rules to administer this section.

(b) Recommend practice standards for the practice of medical physics which are consistent with the Guidelines for Ethical Practice for Medical Physicists prepared by the American Association of Physicists in Medicine and disciplinary guidelines adopted under s. 456.079.

(c) Develop and recommend continuing education requirements for licensed medical physicists.
LICENSE REQUIRED.—An individual may not engage in the practice of medical physics, including the specialties of diagnostic radiological physics, therapeutic radiological physics, medical nuclear radiological physics, or medical health physics, without a license issued by the department for the appropriate specialty.

(a) The department shall adopt rules to administer this section which specify license application and renewal fees, continuing education requirements, and standards for practicing medical physics. The council shall recommend to the department continuing education requirements that shall be a condition of license renewal. The department shall require a minimum of 24 hours per biennium of continuing education offered by an organization recommended by the council and approved by the department. The department, upon recommendation of the council, may adopt rules to specify continuing education requirements for persons who hold a license in more than one specialty.

(e) Upon receipt of an application and fee as specified in this section, the department may issue a license to practice medical physics in this state on or after October 1, 1997, to a person who is board certified in the medical physics specialty in which the applicant applies to practice by the American Board of Radiology for diagnostic radiological physics, therapeutic radiological physics, or medical nuclear radiological physics; by the American Board of Medical Physics for diagnostic radiological physics, therapeutic radiological physics, or medical nuclear radiological physics; or by the American Board of Health Physics or an equivalent certifying body approved by the department.

(k) Upon proof of a completed residency program and receipt of the fee set forth by rule, the department may issue a temporary license for no more than 1 year. The department may adopt by rule requirements for temporary licensure and renewal of temporary licenses.

FEES.—The fee for the initial license application shall be $500 and is nonrefundable. The fee for license renewal may not be more than $500. These fees may cover only the costs incurred by the department and the council to administer this section. By July 1 of each year, the department shall determine whether advise the council if the fees are insufficient to administer this section.

Section 31. Subsection (2) of section 484.047, Florida Statutes, is amended to read:

484.047 Renewal of license.—

(2) In addition to the other requirements for renewal provided in this section and by the board, the department shall renew a license upon receipt of the renewal application and the renewal fee, and a written statement affirming compliance with all other requirements set forth in this section and by the board. A licensee must maintain, if applicable, a certificate from a
manufacturer or independent testing agent certifying that the testing room meets the requirements of s. 484.0501(6) and, if applicable, a certificate from a manufacturer or independent testing agent stating that all audiometric testing equipment used by the licensee has been calibrated acoustically to American National Standards Institute standards on an annual basis. Possession of an applicable certificate is the prerequisite to renewal.

Section 32. Paragraph (a) of subsection (3) of section 486.102, Florida Statutes, is amended to read:

486.102 Physical therapist assistant; licensing requirements.—To be eligible for licensing by the board as a physical therapist assistant, an applicant must:

(3)(a) Have been graduated from a school giving a course of not less than 2 years for physical therapist assistants, which has been approved for the educational preparation of physical therapist assistants by the appropriate accrediting agency recognized by the Commission on Recognition of Postsecondary Accreditation or the United States Department of Education, which includes, but is not limited to, any regional or national institutional accrediting agencies recognized by the United States Department of Education or the Commission on Accreditation for Physical Therapy Education (CAPTE), at the time of her or his graduation and have passed to the satisfaction of the board an examination to determine her or his fitness for practice as a physical therapist assistant as hereinafter provided;

Section 33. Subsections (1) and (4) of section 486.109, Florida Statutes, are amended to read:

486.109 Continuing education.—

(1) The board shall require licensees to periodically demonstrate their professional competence as a condition of renewal of a license by completing 24 hours of continuing education biennially.

(4) Each licensee shall maintain be responsible for maintaining sufficient records in a format as determined by rule which shall be subject to a random audit by the department to demonstrate assure compliance with this section.

Section 34. Paragraph (a) of subsection (15) of section 499.028, Florida Statutes, is amended to read:

499.028 Drug samples or complimentary drugs; starter packs; permits to distribute.—

(15) A person may not possess a prescription drug sample unless:

CODING: Words stricken are deletions; words underlined are additions.
(a) The drug sample was prescribed to her or him as evidenced by the label required in s. 465.0276(4) 465.0276(5).

Section 35. Subsection (3) of section 893.04, Florida Statutes, is amended to read:

893.04 Pharmacist and practitioner.—

(3) Notwithstanding subsection (1), a pharmacist may dispense a one-time emergency refill of up to a 72-hour supply of the prescribed medication for any medicinal drug other than a medicinal drug listed in Schedule II, or up to one vial of insulin to treat diabetes mellitus, in compliance with the provisions of s. 465.0275.

Section 36. Paragraph (g) of subsection (3) of section 921.0022, Florida Statutes, is amended to read:

921.0022 Criminal Punishment Code; offense severity ranking chart.—

(3) OFFENSE SEVERITY RANKING CHART

(g) LEVEL 7

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<td>DUI resulting in serious bodily injury.</td>
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<td>3rd</td>
<td>Medicaid provider fraud; $10,000 or less.</td>
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<td>800.04(5)(c)2.</td>
<td>2nd</td>
<td>Lewd or lascivious molestation; victim 12 years of age or older but younger than 16 years of age; offender 18 years of age or older.</td>
</tr>
<tr>
<td>800.04(5)(e)</td>
<td>1st</td>
<td>Lewd or lascivious molestation; victim 12 years of age or older but younger than 16 years; offender 18 years or older; prior conviction for specified sex offense.</td>
</tr>
<tr>
<td>806.01(2)</td>
<td>2nd</td>
<td>Maliciously damage structure by fire or explosive.</td>
</tr>
<tr>
<td>810.02(3)(a)</td>
<td>2nd</td>
<td>Burglary of occupied dwelling; unarmed; no assault or battery.</td>
</tr>
<tr>
<td>810.02(3)(b)</td>
<td>2nd</td>
<td>Burglary of unoccupied dwelling; unarmed; no assault or battery.</td>
</tr>
<tr>
<td>810.02(3)(d)</td>
<td>2nd</td>
<td>Burglary of occupied conveyance; unarmed; no assault or battery.</td>
</tr>
<tr>
<td>810.02(3)(e)</td>
<td>2nd</td>
<td>Burglary of authorized emergency vehicle.</td>
</tr>
<tr>
<td>812.014(2)(a)1.</td>
<td>1st</td>
<td>Property stolen, valued at $100,000 or more or a semitrailer deployed by a law enforcement officer; property stolen while causing other property damage; 1st degree grand theft.</td>
</tr>
</tbody>
</table>

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<tr>
<td>812.014(2)(b)2.</td>
<td>2nd</td>
<td>Property stolen, cargo valued at less than $50,000, grand theft in 2nd degree.</td>
</tr>
<tr>
<td>812.014(2)(b)3.</td>
<td>2nd</td>
<td>Property stolen, emergency medical equipment; 2nd degree grand theft.</td>
</tr>
<tr>
<td>812.014(2)(b)4.</td>
<td>2nd</td>
<td>Property stolen, law enforcement equipment from authorized emergency vehicle.</td>
</tr>
<tr>
<td>812.0145(2)(a)</td>
<td>1st</td>
<td>Theft from person 65 years of age or older; $50,000 or more.</td>
</tr>
<tr>
<td>812.019(2)</td>
<td>1st</td>
<td>Stolen property; initiates, organizes, plans, etc., the theft of property and traffics in stolen property.</td>
</tr>
<tr>
<td>812.131(2)(a)</td>
<td>2nd</td>
<td>Robbery by sudden snatching.</td>
</tr>
<tr>
<td>812.133(2)(b)</td>
<td>1st</td>
<td>Carjacking; no firearm, deadly weapon, or other weapon.</td>
</tr>
<tr>
<td>817.034(4)(a)1.</td>
<td>1st</td>
<td>Communications fraud, value greater than $50,000.</td>
</tr>
<tr>
<td>817.234(8)(a)</td>
<td>2nd</td>
<td>Solicitation of motor vehicle accident victims with intent to defraud.</td>
</tr>
<tr>
<td>817.234(9)</td>
<td>2nd</td>
<td>Organizing, planning, or participating in an intentional motor vehicle collision.</td>
</tr>
<tr>
<td>817.234(11)(c)</td>
<td>1st</td>
<td>Insurance fraud; property value $100,000 or more.</td>
</tr>
<tr>
<td>817.2341(2)(b) &amp; (3)(b)</td>
<td>1st</td>
<td>Making false entries of material fact or false statements regarding property values relating to the solvency of an insuring entity which are a significant cause of the insolvency of that entity.</td>
</tr>
<tr>
<td>817.535(2)(a)</td>
<td>3rd</td>
<td>Filing false lien or other unauthorized document.</td>
</tr>
<tr>
<td>825.102(3)(b)</td>
<td>2nd</td>
<td>Neglecting an elderly person or disabled adult causing great bodily harm, disability, or disfigurement.</td>
</tr>
<tr>
<td>825.103(3)(b)</td>
<td>2nd</td>
<td>Exploiting an elderly person or disabled adult and property is valued at $10,000 or more, but less than $50,000.</td>
</tr>
</tbody>
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<tr>
<td>827.03(2)(b)</td>
<td>2nd</td>
<td>Neglect of a child causing great bodily harm, disability, or disfigurement.</td>
</tr>
<tr>
<td>827.04(3)</td>
<td>3rd</td>
<td>Impregnation of a child under 16 years of age by person 21 years of age or older.</td>
</tr>
<tr>
<td>837.05(2)</td>
<td>3rd</td>
<td>Giving false information about alleged capital felony to a law enforcement officer.</td>
</tr>
<tr>
<td>838.015</td>
<td>2nd</td>
<td>Bribery.</td>
</tr>
<tr>
<td>838.016</td>
<td>2nd</td>
<td>Unlawful compensation or reward for official behavior.</td>
</tr>
<tr>
<td>838.021(3)(a)</td>
<td>2nd</td>
<td>Unlawful harm to a public servant.</td>
</tr>
<tr>
<td>838.22</td>
<td>2nd</td>
<td>Bid tampering.</td>
</tr>
<tr>
<td>843.0855(2)</td>
<td>3rd</td>
<td>Impersonation of a public officer or employee.</td>
</tr>
<tr>
<td>843.0855(3)</td>
<td>3rd</td>
<td>Unlawful simulation of legal process.</td>
</tr>
<tr>
<td>843.0855(4)</td>
<td>3rd</td>
<td>Intimidation of a public officer or employee.</td>
</tr>
<tr>
<td>847.0135(3)</td>
<td>3rd</td>
<td>Solicitation of a child, via a computer service, to commit an unlawful sex act.</td>
</tr>
<tr>
<td>847.0135(4)</td>
<td>2nd</td>
<td>Traveling to meet a minor to commit an unlawful sex act.</td>
</tr>
<tr>
<td>872.06</td>
<td>2nd</td>
<td>Abuse of a dead human body.</td>
</tr>
<tr>
<td>874.05(2)(b)</td>
<td>1st</td>
<td>Encouraging or recruiting person under 13 to join a criminal gang; second or subsequent offense.</td>
</tr>
<tr>
<td>874.10</td>
<td>1st,PBL</td>
<td>Knowingly initiates, organizes, plans, finances, directs, manages, or supervises criminal gang-related activity.</td>
</tr>
<tr>
<td>893.13(1)(c)</td>
<td>1st</td>
<td>Sell, manufacture, or deliver cocaine (or other drug prohibited under s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)4.) within 1,000 feet of a child care facility, school, or state, county, or municipal park or publicly owned recreational facility or community center.</td>
</tr>
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<tr>
<td>893.13(1)(e)1.</td>
<td>1st</td>
<td>Sell, manufacture, or deliver cocaine or other drug prohibited under s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)4., within 1,000 feet of property used for religious services or a specified business site.</td>
</tr>
<tr>
<td>893.13(4)(a)</td>
<td>1st</td>
<td>Deliver to minor cocaine (or other s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)4. drugs).</td>
</tr>
<tr>
<td>893.135(1)(a)1.</td>
<td>1st</td>
<td>Trafficking in cannabis, more than 25 lbs., less than 2,000 lbs.</td>
</tr>
<tr>
<td>893.135(1)(b)1.a.</td>
<td>1st</td>
<td>Trafficking in cocaine, more than 28 grams, less than 200 grams.</td>
</tr>
<tr>
<td>893.135(1)(c)1.a.</td>
<td>1st</td>
<td>Trafficking in illegal drugs, more than 4 grams, less than 14 grams.</td>
</tr>
<tr>
<td>893.135(1)(c)2.a.</td>
<td>1st</td>
<td>Trafficking in hydrocodone, 14 grams or more, less than 28 grams.</td>
</tr>
<tr>
<td>893.135(1)(c)2.b.</td>
<td>1st</td>
<td>Trafficking in hydrocodone, 28 grams or more, less than 50 grams.</td>
</tr>
<tr>
<td>893.135(1)(c)3.a.</td>
<td>1st</td>
<td>Trafficking in oxycodone, 7 grams or more, less than 14 grams.</td>
</tr>
<tr>
<td>893.135(1)(c)3.b.</td>
<td>1st</td>
<td>Trafficking in oxycodone, 14 grams or more, less than 25 grams.</td>
</tr>
<tr>
<td>893.135(1)(d)1.</td>
<td>1st</td>
<td>Trafficking in phencyclidine, more than 28 grams, less than 200 grams.</td>
</tr>
<tr>
<td>893.135(1)(e)1.</td>
<td>1st</td>
<td>Trafficking in methaqualone, more than 200 grams, less than 5 kilograms.</td>
</tr>
<tr>
<td>893.135(1)(f)1.</td>
<td>1st</td>
<td>Trafficking in amphetamine, more than 14 grams, less than 28 grams.</td>
</tr>
<tr>
<td>893.135(1)(g)1.a.</td>
<td>1st</td>
<td>Trafficking in flunitrazepam, 4 grams or more, less than 14 grams.</td>
</tr>
<tr>
<td>893.135(1)(h)1.a.</td>
<td>1st</td>
<td>Trafficking in gamma-hydroxybutyric acid (GHB), 1 kilogram or more, less than 5 kilograms.</td>
</tr>
<tr>
<td>893.135(1)(j)1.a.</td>
<td>1st</td>
<td>Trafficking in 1,4-Butanediol, 1 kilogram or more, less than 5 kilograms.</td>
</tr>
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<tr>
<td>893.135(1)(k)2.a.</td>
<td>1st</td>
<td>Trafficking in Phenethylamines, 10 grams or more, less than 200 grams.</td>
</tr>
<tr>
<td>893.1351(2)</td>
<td>2nd</td>
<td>Possession of place for trafficking in or manufacturing of controlled substance.</td>
</tr>
<tr>
<td>896.101(5)(a)</td>
<td>3rd</td>
<td>Money laundering, financial transactions exceeding $300 but less than $20,000.</td>
</tr>
<tr>
<td>896.104(4)(a)1.</td>
<td>3rd</td>
<td>Structuring transactions to evade reporting or registration requirements, financial transactions exceeding $300 but less than $20,000.</td>
</tr>
<tr>
<td>943.0435(4)(c)</td>
<td>2nd</td>
<td>Sexual offender vacating permanent residence; failure to comply with reporting requirements.</td>
</tr>
<tr>
<td>943.0435(8)</td>
<td>2nd</td>
<td>Sexual offender; remains in state after indicating intent to leave; failure to comply with reporting requirements.</td>
</tr>
<tr>
<td>943.0435(9)(a)</td>
<td>3rd</td>
<td>Sexual offender; failure to comply with reporting requirements.</td>
</tr>
<tr>
<td>943.0435(13)</td>
<td>3rd</td>
<td>Failure to report or providing false information about a sexual offender; harbor or conceal a sexual offender.</td>
</tr>
<tr>
<td>943.0435(14)</td>
<td>3rd</td>
<td>Sexual offender; failure to report and reregister; failure to respond to address verification; providing false registration information.</td>
</tr>
<tr>
<td>944.607(9)</td>
<td>3rd</td>
<td>Sexual offender; failure to comply with reporting requirements.</td>
</tr>
<tr>
<td>944.607(10)(a)</td>
<td>3rd</td>
<td>Sexual offender; failure to submit to the taking of a digitized photograph.</td>
</tr>
<tr>
<td>944.607(12)</td>
<td>3rd</td>
<td>Failure to report or providing false information about a sexual offender; harbor or conceal a sexual offender.</td>
</tr>
<tr>
<td>944.607(13)</td>
<td>3rd</td>
<td>Sexual offender; failure to report and reregister; failure to respond to address verification; providing false registration information.</td>
</tr>
<tr>
<td>985.4815(10)</td>
<td>3rd</td>
<td>Sexual offender; failure to submit to the taking of a digitized photograph.</td>
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<tr>
<td>985.4815(12)</td>
<td>3rd</td>
<td>Failure to report or providing false information about a sexual offender; harbor or conceal a sexual offender.</td>
</tr>
<tr>
<td>985.4815(13)</td>
<td>3rd</td>
<td>Sexual offender; failure to report and reregister; failure to respond to address verification; providing false registration information.</td>
</tr>
</tbody>
</table>

Section 37. This act shall take effect July 1, 2016.

Approved by the Governor April 14, 2016.

Filed in Office Secretary of State April 14, 2016.
CHAPTER 2016-212

Committee Substitute for Committee
Substitute for Senate Bill No. 1604

An act relating to drugs, devices, and cosmetics; amending s. 385.211, F.S.; authorizing a certain type of specialty hospital to conduct research on cannabidiol and low-THC cannabis if contracted with the Department of Health to perform such research; amending s. 499.003, F.S.; providing, revising, and deleting definitions for purposes of the Florida Drug and Cosmetic Act; requiring rulemaking; specifying a default rule until the Department of Business and Professional Regulation adopts a rule; amending s. 499.005, F.S.; revising prohibited acts related to the distribution of prescription drugs; conforming a cross-reference; amending s. 499.0051, F.S.; prohibiting the distribution of prescription drugs without delivering a transaction history, transaction information, and transaction statement; providing penalties; deleting provisions and revising terminology related to pedigree papers, to conform to changes made by the act; amending s. 499.006, F.S.; conforming provisions; amending s. 499.01, F.S.; requiring nonresident prescription drug repackagers to obtain an operating permit; authorizing a manufacturer to engage in the wholesale distribution of prescription drugs; providing for the issuance of virtual prescription drug manufacturer permits and virtual nonresident prescription drug manufacturer permits to certain persons; providing exceptions from certain virtual manufacturer requirements; requiring a nonresident prescription drug repacker permit for certain persons; deleting surety bond requirements for prescription drug wholesale distributors; requiring that certain persons obtain an out-of-state prescription drug wholesale distributor permit; providing that a restricted prescription drug distributor permit is not required for distributions between certain pharmacies; requiring the Department of Business and Professional Regulation to establish by rule when such distribution constitutes regular and systematic supplying of a prescription drug; requiring certain third party logistic providers to be licensed; requiring research and development labeling on certain prescription drug active pharmaceutical ingredient packaging; requiring certain manufacturers to create and maintain certain records; requiring certain prescription drug distributors to provide certain information to health care entities for which they repackage prescription drugs; requiring the department to adopt rules concerning repackaged prescription drug safety and integrity; amending s. 499.012, F.S.; providing for issuance of a prescription drug manufacturer permit or retail pharmacy drug wholesale distributor permit when an applicant at the same address is a licensed nuclear pharmacy or community pharmacy; providing for the expiration of deficient permit applications; requiring trade secret information submitted by an applicant to be maintained as a trade secret; authorizing the quadrennial renewal of permits; providing for calculation of fees for such permit renewals; revising procedures and application requirements for

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permit renewals; providing for late renewal fees; allowing a permittee who submits a renewal application to continue operations; removing certain application requirements for renewal of a permit; requiring bonds or other surety of a specified amount; requiring proof of inspection of establishments used in wholesale distribution; authorizing the Department of Business and Professional Regulation to contract for the collection of electronic fingerprints under certain circumstances; providing information that may be submitted in lieu of certain application requirements for specified permits and certifications; removing provisions relating to annual renewal and expiration of permits; conforming cross-references; amending s. 499.01201, F.S.; conforming provisions; amending s. 499.0121, F.S.; revising prescription drug recordkeeping requirements; specifying recordkeeping requirements for manufacturers and repackers of medical devices, over-the-counter drugs, and cosmetics; increasing the quantity of unit doses of a controlled substance that may be ordered in any given month by a customer without triggering a requirement that a wholesale distributor perform a reasonableness assessment; conforming provisions; amending s. 499.015, F.S.; providing for the expiration, renewal, and issuance of certain drug, device, and cosmetic product registrations; providing for product registration fees; amending ss. 499.03, 499.05, and 499.051, F.S.; conforming provisions to changes made by the act; amending s. 499.82, F.S.; revising the definition of “wholesale distribution” for purposes of medical gas requirements; amending s. 499.83, F.S.; authorizing licensed hospices to obtain on behalf of, and sell medical oxygen to, their patients without obtaining a medical oxygen retail establishment permit in certain circumstances; specifying recordkeeping requirements; amending s. 499.89, F.S.; conforming provisions; repealing s. 499.01212, F.S., relating to pedigree papers; amending ss. 409.9201, 499.067, 794.075, and 921.0022, F.S.; conforming cross-references; creating s. 893.30, F.S.; creating the “Victoria Siegel Controlled Substances Safety Education and Awareness Act”; requiring the Department of Health to develop an educational pamphlet relating to certain controlled substance issues; requiring the department to encourage health care providers to disseminate certain educational information; requiring the department to encourage consumers to discuss controlled substance risks with certain health care providers; requiring the State Surgeon General to provide certain educational resources on the department’s website; requiring the department to fund controlled substance safety education and awareness with certain grants; encouraging the department to collaborate with other entities to create a systematic approach to increasing public awareness regarding controlled substance safety; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (2) of section 385.211, Florida Statutes, is amended to read:

CODING: Words stricken are deletions; words underlined are additions.
385.211 Refractory and intractable epilepsy treatment and research at recognized medical centers.—

(2) Notwithstanding chapter 893, medical centers recognized pursuant to s. 381.925, or an academic medical research institution legally affiliated with a licensed children’s specialty hospital as defined in s. 395.002(28) that contracts with the Department of Health, may conduct research on cannabidiol and low-THC cannabis. This research may include, but is not limited to, the agricultural development, production, clinical research, and use of liquid medical derivatives of cannabidiol and low-THC cannabis for the treatment for refractory or intractable epilepsy. The authority for recognized medical centers to conduct this research is derived from 21 C.F.R. parts 312 and 316. Current state or privately obtained research funds may be used to support the activities described in this section.

Section 2. Section 499.003, Florida Statutes, is amended to read:

499.003 Definitions of terms used in this part.—As used in this part, the term:

(1) “Active pharmaceutical ingredient” includes any substance or mixture of substances intended, represented, or labeled for use in drug manufacturing that furnishes or is intended to furnish, in a finished dosage form, any pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals, or to affect the structure or any function of the body of humans or animals.

(2) “Advertisement” means any representation disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of drugs, devices, or cosmetics.

(3) “Affiliate” means a business entity that has a relationship with another business entity in which, directly or indirectly:

(a) The business entity controls, or has the power to control, the other business entity; or

(b) A third party controls, or has the power to control, both business entities.

(2) “Affiliated group” means an affiliated group as defined by s. 1504 of the Internal Revenue Code of 1986, as amended, which is composed of chain drug entities, including at least 50 retail pharmacies, warehouses, or repackagers, which are members of the same affiliated group. The affiliated group must disclose the names of all its members to the department.

(4) “Affiliated party” means:

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(a) A director, officer, trustee, partner, or committee member of a permittee or applicant or a subsidiary or service corporation of the permittee or applicant;

(b) A person who, directly or indirectly, manages, controls, or oversees the operation of a permittee or applicant, regardless of whether such person is a partner, shareholder, manager, member, officer, director, independent contractor, or employee of the permittee or applicant;

(c) A person who has filed or is required to file a personal information statement pursuant to s. 499.012(9) or is required to be identified in an application for a permit or to renew a permit pursuant to s. 499.012(8); or

(d) The five largest natural shareholders that own at least 5 percent of the permittee or applicant.

(5)(4) “Applicant” means a person applying for a permit or certification under this part.

(5) “Authenticate” means to affirmatively verify upon receipt of a prescription drug that each transaction listed on the pedigree paper has occurred.

(a) A wholesale distributor is not required to open a sealed, medical convenience kit to authenticate a pedigree paper for a prescription drug contained within the kit.

(b) Authentication of a prescription drug included in a sealed, medical convenience kit shall be limited to verifying the transaction and pedigree information received.

(6) “Certificate of free sale” means a document prepared by the department which certifies a drug, device, or cosmetic, that is registered with the department, as one that can be legally sold in the state.

(7) “Chain pharmacy warehouse” means a wholesale distributor permitted pursuant to s. 499.01 that maintains a physical location for prescription drugs that functions solely as a central warehouse to perform intracompany transfers of such drugs between members of an affiliate to a member of its affiliated group.

(8) “Closed pharmacy” means a pharmacy that is licensed under chapter 465 and purchases prescription drugs for use by a limited patient population and not for wholesale distribution or sale to the public. The term does not include retail pharmacies.

(9) “Color” includes black, white, and intermediate grays.

(10) “Color additive” means, with the exception of any material that has been or hereafter is exempt under the federal act, a material that:
(a) Is a dye pigment, or other substance, made by a process of synthesis
or similar artifice, or extracted, isolated, or otherwise derived, with or
without intermediate or final change of identity from a vegetable, animal,
mineral, or other source; or

(b) When added or applied to a drug or cosmetic or to the human body, or
any part thereof, is capable alone, or through reaction with other substances,
of imparting color thereto.

(11) “Contraband prescription drug” means any adulterated drug, as
defined in s. 499.006, any counterfeit drug, as defined in this section, and
also means any prescription drug for which a transaction history, transac-
tion information, or transaction statement pedigree paper does not exist, or
for which the transaction history, transaction information, or transaction
statement pedigree paper in existence has been forged, counterfeited, falsely
created, or contains any altered, false, or misrepresented matter.

(12) “Cosmetic” means an article, with the exception of soap, that is:

(a) Intended to be rubbed, poured, sprinkled, or sprayed on; introduced
into; or otherwise applied to the human body or any part thereof for
cleansing, beautifying, promoting attractiveness, or altering the appear-
ance; or

(b) Intended for use as a component of any such article.

(13) “Counterfeit drug,” “counterfeit device,” or “counterfeit cosmetic”
means a drug, device, or cosmetic which, or the container, seal, or labeling of
which, without authorization, bears the trademark, trade name, or other
identifying mark, imprint, or device, or any likeness thereof, of a drug,
device, or cosmetic manufacturer, processor, packer, or distributor other
than the person that in fact manufactured, processed, packed, or distributed
that drug, device, or cosmetic and which thereby falsely purports or is
represented to be the product of, or to have been packed or distributed by,
that other drug, device, or cosmetic manufacturer, processor, packer, or
distributor.

(14) “Department” means the Department of Business and Professional
Regulation.

(15) “Device” means any instrument, apparatus, implement, machine,
contrivance, implant, in vitro reagent, or other similar or related article,
including its components, parts, or accessories, which is:

(a) Recognized in the current edition of the United States Pharma-
copoeia and National Formulary, or any supplement thereof,

(b) Intended for use in the diagnosis, cure, mitigation, treatment,
therapy, or prevention of disease in humans or other animals, or
(c) Intended to affect the structure or any function of the body of humans or other animals,

and that does not achieve any of its principal intended purposes through chemical action within or on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

(16) “Distribute” or “distribution” means to sell, purchase, trade, deliver, handle, store, or receive to sell; offer to sell; give away; transfer, whether by passage of title, physical movement, or both; deliver; or offer to deliver. The term does not mean to administer or dispense and does not include the billing and invoicing activities that commonly follow a wholesale distribution transaction.

(17) “Drop shipment” means the sale of a prescription drug from a manufacturer to a wholesale distributor, where the wholesale distributor takes title to, but not possession of, the prescription drug, and the manufacturer of the prescription drug ships the prescription drug directly to a chain pharmacy warehouse or a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug, as defined in s. 465.003.

(17)(18) “Drug” means an article that is:

(a) Recognized in the current edition of the United States Pharmacopeia and National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of those publications;

(b) Intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals;

(c) Intended to affect the structure or any function of the body of humans or other animals; or

(d) Intended for use as a component of any article specified in paragraph (a), paragraph (b), or paragraph (c), and includes active pharmaceutical ingredients, but does not include devices or their nondrug components, parts, or accessories. For purposes of this paragraph, an “active pharmaceutical ingredient” includes any substance or mixture of substances intended, represented, or labeled for use in drug manufacturing that furnishes or is intended to furnish, in a finished dosage form, any pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals, or to affect the structure or any function of the body of humans or other animals.

(18)(19) “Establishment” means a place of business which is at one general physical location and may extend to one or more contiguous suites, units, floors, or buildings operated and controlled exclusively by entities under common operation and control. Where multiple buildings are under

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common exclusive ownership, operation, and control, an intervening thoroughfare does not affect the contiguous nature of the buildings. For purposes of permitting, each suite, unit, floor, or building must be identified in the most recent permit application.


(20)(21) “Freight forwarder” means a person who receives prescription drugs which are owned by another person and designated by that person for export, and exports those prescription drugs.

(21)(22) “Health care entity” means a closed pharmacy or any person, organization, or business entity that provides diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care, but does not include any wholesale distributor or retail pharmacy licensed under state law to deal in prescription drugs. However, a blood establishment is a health care entity that may engage in the wholesale distribution of prescription drugs under s. 499.01(2)(h)1.c. 499.01(2)(g)1.c.

(22)(23) “Health care facility” means a health care facility licensed under chapter 395.

(23)(24) “Hospice” means a corporation licensed under part IV of chapter 400.

(24)(25) “Hospital” means a facility as defined in s. 395.002 and licensed under chapter 395.

(25)(26) “Immediate container” does not include package liners.

(26)(27) “Label” means a display of written, printed, or graphic matter upon the immediate container of any drug, device, or cosmetic. A requirement made by or under authority of this part or rules adopted under this part that any word, statement, or other information appear on the label is not complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such drug, device, or cosmetic or is easily legible through the outside container or wrapper.

(27)(28) “Labeling” means all labels and other written, printed, or graphic matters:

(a) Upon a drug, device, or cosmetic, or any of its containers or wrappers; or

(b) Accompanying or related to such drug, device, or cosmetic.

(28)(29) “Manufacture” means the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any drug, device, or cosmetic.

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“Manufacturer” means:

(a) A person who holds a New Drug Application, an Abbreviated New Drug Application, a Biologics License Application, or a New Animal Drug Application approved under the federal act or a license issued under s. 351 of the Public Health Service Act, 42 U.S.C. s. 262, for such drug or biologics, or if such drug or biologics are not the subject of an approved application or license, the person who manufactured the drug or biologics prepares, derives, manufactures, or produces a drug, device, or cosmetic;

(b) A co-licensed partner of the person described in paragraph (a) who obtains the drug or biologics directly from a person described in paragraph (a), paragraph (c), or this paragraph The holder or holders of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), a Biologics License Application (BLA), or a New Animal Drug Application (NADA), provided such application has become effective or is otherwise approved consistent with s. 499.023;

(c) An affiliate of a person described in paragraph (a), paragraph (b), or this paragraph that receives the drug or biologics directly from a person described in paragraph (a), paragraph (b), or this paragraph A private label distributor for whom the private label distributor’s prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged; or

(d) A person who manufactures a device or a cosmetic. A person registered under the federal act as a manufacturer of a prescription drug, who is described in paragraph (a), paragraph (b), or paragraph (c), who has entered into a written agreement with another prescription drug manufacturer that authorizes either manufacturer to distribute the prescription drug identified in the agreement as the manufacturer of that drug consistent with the federal act and its implementing regulations;

(e) A member of an affiliated group that includes, but is not limited to, persons described in paragraph (a), paragraph (b), paragraph (c), or paragraph (d), which member distributes prescription drugs, whether or not obtaining title to the drugs, only for the manufacturer of the drugs who is also a member of the affiliated group. As used in this paragraph, the term “affiliated group” means an affiliated group as defined in s. 1504 of the Internal Revenue Code of 1986, as amended. The manufacturer must disclose the names of all of its affiliated group members to the department; or

(f) A person permitted as a third party logistics provider, only while providing warehousing, distribution, or other logistics services on behalf of a person described in paragraph (a), paragraph (b), paragraph (c), paragraph (d), or paragraph (e).

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The term does not include a pharmacy that is operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter.

(30)(31) “Medical convenience kit” means packages or units that contain combination products as defined in 21 C.F.R. s. 3.2(e)(2).

(31)(32) “Medical gas” means any liquefied or vaporized gas that is a prescription drug, whether alone or in combination with other gases, and as defined in the federal act.

(32)(33) “New drug” means:

(a) Any drug the composition of which is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling of that drug; or

(b) Any drug the composition of which is such that the drug, as a result of investigations to determine its safety and effectiveness for use under certain conditions, has been recognized for use under such conditions, but which drug has not, other than in those investigations, been used to a material extent or for a material time under such conditions.

(34) “Normal distribution chain” means a wholesale distribution of a prescription drug in which the wholesale distributor or its wholly owned subsidiary purchases and receives the specific unit of the prescription drug directly from the manufacturer and distributes the prescription drug directly, or through up to two intracompany transfers, to a chain pharmacy warehouse or a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug, as defined in s. 465.003. For purposes of this subsection, the term “intracompany” means any transaction or transfer between any parent, division, or subsidiary wholly owned by a corporate entity.

(33)(35) “Nursing home” means a facility licensed under part II of chapter 400.


(37) “Pedigree paper” means a document in written or electronic form approved by the department which contains information required by s. 499.01212 regarding the sale and distribution of any given prescription drug.

(35)(38) “Permittee” means any person holding a permit issued under this chapter pursuant to s. 499.012.
“Person” means any individual, child, joint venture, syndicate, fiduciary, partnership, corporation, division of a corporation, firm, trust, business trust, company, estate, public or private institution, association, organization, group, city, county, city and county, political subdivision of this state, other governmental agency within this state, and any representative, agent, or agency of any of the foregoing, or any other group or combination of the foregoing.

“Pharmacist” means a person licensed under chapter 465.

“Pharmacy” means an entity licensed under chapter 465.

“Prepackaged drug product” means a drug that originally was in finished packaged form sealed by a manufacturer and that is placed in a properly labeled container by a pharmacy or practitioner authorized to dispense pursuant to chapter 465 for the purpose of dispensing in the establishment in which the prepackaging occurred.

“Prescription drug” means a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active pharmaceutical ingredients subject to, defined by, or described by s. 503(b) of the federal act or s. 465.003(8), s. 499.007(13), subsection (31) (32), or subsection (47) (52), except that an active pharmaceutical ingredient is a prescription drug only if substantially all finished dosage forms in which it may be lawfully dispensed or administered in this state are also prescription drugs.

“Prescription drug label” means any display of written, printed, or graphic matter upon the immediate container of any prescription drug before it is dispensed prior to its dispensing to an individual patient pursuant to a prescription of a practitioner authorized by law to prescribe.

“Prescription label” means any display of written, printed, or graphic matter upon the immediate container of any prescription drug dispensed pursuant to a prescription of a practitioner authorized by law to prescribe.

“Primary wholesale distributor” means any wholesale distributor that:

(a) Purchased 90 percent or more of the total dollar volume of its purchases of prescription drugs directly from manufacturers in the previous year; and

(b) 1. Directly purchased prescription drugs from not fewer than 50 different prescription drug manufacturers in the previous year; or

2. Has, or the affiliated group, as defined in s. 1504 of the Internal Revenue Code, of which the wholesale distributor is a member has, not fewer than 250 employees.
(c) For purposes of this subsection, “directly from manufacturers” means:

1. Purchases made by the wholesale distributor directly from the manufacturer of prescription drugs; and

2. Transfers from a member of an affiliated group, as defined in s. 1504 of the Internal Revenue Code, of which the wholesale distributor is a member, if:

   a. The affiliated group purchases 90 percent or more of the total dollar volume of its purchases of prescription drugs from the manufacturer in the previous year; and

   b. The wholesale distributor discloses to the department the names of all members of the affiliated group of which the wholesale distributor is a member and the affiliated group agrees in writing to provide records on prescription drug purchases by the members of the affiliated group not later than 48 hours after the department requests access to such records, regardless of the location where the records are stored.

(43)(47) “Proprietary drug,” or “OTC drug,” means a patent or over-the-counter drug in its unbroken, original package, which drug is sold to the public by, or under the authority of, the manufacturer or primary distributor thereof, is not misbranded under the provisions of this part, and can be purchased without a prescription.

(44)(48) “Repackage” includes repacking or otherwise changing the container, wrapper, or labeling to further the distribution of the drug, device, or cosmetic.

(45)(49) “Repackager” means a person who repackages. The term excludes pharmacies that are operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter.

(46)(50) “Retail pharmacy” means a community pharmacy licensed under chapter 465 that purchases prescription drugs at fair market prices and provides prescription services to the public.

(51) “Secondary wholesale distributor” means a wholesale distributor that is not a primary wholesale distributor.

(47)(52) “Veterinary prescription drug” means a prescription drug intended solely for veterinary use. The label of the drug must bear the statement, “Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian.”

(48)(53) “Wholesale distribution” means the distribution of a prescription drug to a person other than a consumer or patient, or

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the receipt of a prescription drug by a person other than the consumer or patient, but does not include:

(a) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with s. 499.01(2)(h) 499.01(2)(g):

1. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of that organization.

2. The distribution sale, purchase, or trade of a prescription drug or an offer to distribute sell, purchase, or trade a prescription drug by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended and revised, to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

3. The distribution sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control. For purposes of this subparagraph, “common control” means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise.

4. The distribution sale, purchase, trade, or other transfer of a prescription drug from or for any federal, state, or local government agency or any entity eligible to purchase prescription drugs at public health services prices pursuant to Pub. L. No. 102-585, s. 602 to a contract provider or its subcontractor for eligible patients of the agency or entity under the following conditions:

   a. The agency or entity must obtain written authorization for the distribution sale, purchase, trade, or other transfer of a prescription drug under this subparagraph from the Secretary of Business and Professional Regulation or his or her designee.

   b. The contract provider or subcontractor must be authorized by law to administer or dispense prescription drugs.

   c. In the case of a subcontractor, the agency or entity must be a party to and execute the subcontract.

   d. The contract provider and subcontractor must maintain and produce immediately for inspection all records of movement or transfer of all the prescription drugs belonging to the agency or entity, including, but not limited to, the records of receipt and disposition of prescription drugs. Each contractor and subcontractor dispensing or administering these drugs must maintain and produce records documenting the dispensing or administration. Records that are required to be maintained include, but are not limited to, a perpetual inventory itemizing drugs received and drugs dispensed by
prescription number or administered by patient identifier, which must be submitted to the agency or entity quarterly.

e. The contract provider or subcontractor may administer or dispense the prescription drugs only to the eligible patients of the agency or entity or must return the prescription drugs for or to the agency or entity. The contract provider or subcontractor must require proof from each person seeking to fill a prescription or obtain treatment that the person is an eligible patient of the agency or entity and must, at a minimum, maintain a copy of this proof as part of the records of the contractor or subcontractor required under sub-subparagraph d.

f. In addition to the departmental inspection authority set forth in s. 499.051, the establishment of the contract provider and subcontractor and all records pertaining to prescription drugs subject to this subparagraph shall be subject to inspection by the agency or entity. All records relating to prescription drugs of a manufacturer under this subparagraph shall be subject to audit by the manufacturer of those drugs, without identifying individual patient information.

(b) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with rules established by the department:

1. The distribution sale, purchase, or trade of a prescription drug among federal, state, or local government health care entities that are under common control and are authorized to purchase such prescription drug.

2. The distribution sale, purchase, or trade of a prescription drug or an offer to distribute sell, purchase, or trade a prescription drug for emergency medical reasons, which may include. For purposes of this subparagraph, The term “emergency medical reasons” includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage. For purposes of this subparagraph, a drug shortage not caused by a public health emergency does not constitute an emergency medical reason.

3. The distribution transfer of a prescription drug acquired by a medical director on behalf of a licensed emergency medical services provider to that emergency medical services provider and its transport vehicles for use in accordance with the provider's license under chapter 401.

4. The revocation of a sale or the return of a prescription drug to the person's prescription drug wholesale supplier.

4.5. The donation of a prescription drug by a health care entity to a charitable organization that has been granted an exemption under s. 501(c)(3) of the Internal Revenue Code of 1986, as amended, and that is authorized to possess prescription drugs.

5.6. The distribution transfer of a prescription drug by a person authorized to purchase or receive prescription drugs to a person licensed
or permitted to handle reverse distributions or destruction under the laws of
the jurisdiction in which the person handling the reverse distribution or
destruction receives the drug.

6.7. The distribution transfer of a prescription drug by a hospital or other
health care entity to a person licensed under this part to repackage
prescription drugs for the purpose of repackaging the prescription drug
for use by that hospital, or other health care entity and other health care
entities that are under common control, if ownership of the prescription
drugs remains with the hospital or other health care entity at all times. In
addition to the recordkeeping requirements of s. 499.0121(6), the hospital or
health care entity that distributes transfers prescription drugs pursuant to
this subparagraph must reconcile all drugs distributed transferred and
returned and resolve any discrepancies in a timely manner.

(c) Intracompany distribution of any drug between members of an
affiliate or within a manufacturer.

(d) The distribution of a prescription drug by the manufacturer of the
prescription drug.

(e) The distribution of prescription drug samples by manufacturers’
representatives or distributors’ representatives conducted in accordance
with s. 499.028.

(f) The distribution of a prescription drug by a third-party logistics
provider permitted or licensed pursuant to and operating in compliance with
the laws of this state and federal law if such third-party logistics provider
does not take ownership of the prescription drug.

(g) The distribution of a prescription drug, or an offer to distribute a
prescription drug by a repackager registered as a drug establishment with
the United States Food and Drug Administration that has taken ownership
or possession of the prescription drug and repacks it in accordance with this
part.

(h) The purchase or other acquisition by a dispenser, hospital, or other
health care entity of a prescription drug for use by such dispenser, hospital,
or other health care entity.

(i) The distribution of a prescription drug by a hospital or other health
care entity, or by a wholesale distributor or manufacturer operating at the
direction of the hospital or other health care entity, to a repackager for the
purpose of repackaging the prescription drug for use by that hospital, or
other health care entity and other health care entities that are under
common control, if ownership of the prescription drug remains with the
hospital or other health care entity at all times.

(j) The distribution sale, purchase, or trade of blood and blood
components intended for transfusion. As used in this paragraph, the term
“blood” means whole blood collected from a single donor and processed for
transfusion or further manufacturing, and the term “blood components” means that part of the blood separated by physical or mechanical means.

(k)(e) The lawful dispensing of a prescription drug in accordance with chapter 465.

(l)(f) The distribution sale, purchase, or trade of a prescription drug between pharmacies as a result of a sale, transfer, merger, or consolidation of all or part of the business of the pharmacies from or with another pharmacy, whether accomplished as a purchase and sale of stock or of business assets.

(m) The distribution of minimal quantities of prescription drugs by a licensed retail pharmacy to a licensed practitioner for office use in compliance with chapter 465 and rules adopted thereunder. The department shall adopt rules specifying the quantities of prescription drugs which are considered to be minimal quantities. However, until such rules are adopted, minimal quantities distributed may not exceed 3 percent of the retail pharmacy’s total annual purchases of prescription drugs.

(n) The distribution of an intravenous prescription drug that, by its formulation, is intended for the replenishment of fluids and electrolytes, such as sodium, chloride, and potassium or calories, such as dextrose and amino acids.

(o) The distribution of an intravenous prescription drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions.

(p) The distribution of a prescription drug that is intended for irrigation or sterile water, whether intended for such purposes or for injection.

(q) The distribution of an exempt medical convenience kit pursuant to 21 U.S.C. s. 353(e)(4)(M).

(r) A common carrier that transports a prescription drug, if the common carrier does not take ownership of the prescription drug.

(s) Saleable drug returns when conducted by a dispenser.

(t) Facilitating the distribution of a prescription drug by providing solely administrative services, including processing of orders and payments.

(u) The distribution by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of prescription drugs donated to or supplied at a reduced price to the charitable organization to:

1. A licensed health care practitioner, as defined in s. 456.001, who is authorized under the appropriate practice act to prescribe and administer prescription drugs;

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2. A health care clinic establishment permitted pursuant to chapter 499; or

3. The Department of Health or the licensed medical director of a government agency health care entity, authorized to possess prescription drugs, for storage and use in the treatment of persons in need of emergency medical services, including controlling communicable diseases or providing protection from unsafe conditions that pose an imminent threat to public health,

if the distributor and the receiving entity receive no direct or indirect financial benefit other than tax benefits related to charitable contributions. Distributions under this section that involve controlled substances must comply with all state and federal regulations pertaining to the handling of controlled substances.

(v) The distribution of medical gas pursuant to part III of this chapter.

"Wholesale distributor" means any person, other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or a repackager, who is engaged in wholesale distribution of prescription drugs in or into this state, including, but not limited to, manufacturers; repackagers; own-label distributors; jobbers; private-label distributors; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; exporters; retail pharmacies; and the agents thereof that conduct wholesale distributions.

Section 3. Subsections (21), (28), and (29) of section 499.005, Florida Statutes, are amended to read:

499.005 Prohibited acts.—It is unlawful for a person to perform or cause the performance of any of the following acts in this state:

(21) The wholesale distribution of any prescription drug that was:

(a) Purchased by a public or private hospital or other health care entity; or

(b) Donated or supplied at a reduced price to a charitable organization, unless the wholesale distribution of the prescription drug is authorized in s. 499.01(2)(h)1.c. 499.01(2)(g)1.c.

(28) Failure to acquire or deliver a transaction history, transaction information, or transaction statement pedigree paper as required under this part and rules adopted under this part.

(29) The receipt of a prescription drug pursuant to a wholesale distribution without having previously received or simultaneously receiving
Section 4. Subsections (4) through (17) of section 499.0051, Florida Statutes, are renumbered as subsections (3) through (16), respectively, and subsections (1) and (2), present subsection (3), paragraphs (h) and (i) of present subsection (12), paragraph (d) of present subsection (13), and present subsection (15) of that section are amended, to read:

499.0051 Criminal acts.—

(1) FAILURE TO MAINTAIN OR DELIVER TRANSACTION HISTORY, TRANSACTION INFORMATION, OR TRANSACTION STATEMENT PEDIGREE PAPERS.—

(a) A person, other than a manufacturer, engaged in the wholesale distribution of prescription drugs who fails to deliver to another person a complete and accurate transaction history, transaction information, or transaction statement pedigree papers concerning a prescription drug or contraband prescription drug, as required by this chapter and rules adopted under this chapter, before prior to, or simultaneous with, the transfer of the prescription drug or contraband prescription drug to another person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b) A person engaged in the wholesale distribution of prescription drugs who fails to acquire a complete and accurate transaction history, transaction information, or transaction statement pedigree papers concerning a prescription drug or contraband prescription drug, as required by this chapter and rules adopted under this chapter, before prior to, or simultaneous with, the receipt of the prescription drug or contraband prescription drug from another person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(c) Any person who knowingly destroys, alters, conceals, or fails to maintain a complete and accurate transaction history, transaction information, or transaction statement pedigree papers concerning any prescription drug or contraband prescription drug, as required by this chapter and rules adopted under this chapter, in his or her possession commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(2) FAILURE TO AUTHENTICATE PEDIGREE PAPERS.—Effective July 1, 2006:

(a) A person engaged in the wholesale distribution of prescription drugs who is in possession of pedigree papers concerning prescription drugs or contraband prescription drugs and who fails to authenticate the matters contained in the pedigree papers and who nevertheless attempts to further distribute prescription drugs or contraband prescription drugs commits a
felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b) A person in possession of pedigree papers concerning prescription drugs or contraband prescription drugs who falsely swears or certifies that he or she has authenticated the matters contained in the pedigree papers commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(2)(3) KNOWING FORGERY OF TRANSACTION HISTORY, TRANSACTION INFORMATION, OR TRANSACTION STATEMENT PEDIGREE PAPERS.—A person who knowingly forges, counterfeits, or falsely creates any transaction history, transaction information, or transaction statement pedigree paper; who falsely represents any factual matter contained on any transaction history, transaction information, or transaction statement pedigree paper; or who knowingly omits to record material information required to be recorded in a transaction history, transaction information, or transaction statement pedigree paper, commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(11)(12) ADULTERATED AND MISBRANDED DRUGS; FALSE ADVERTISEMENT; FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS.—Any person who violates any of the following provisions commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083; but, if the violation is committed after a conviction of such person under this subsection has become final, such person commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, or as otherwise provided in this part:

(h) The failure to maintain records related to a drug as required by this part and rules adopted under this part, except for transaction histories, transaction information, or transaction statements pedigree papers, invoices, or shipping documents related to prescription drugs.

(i) The possession of any drug in violation of this part, except if the violation relates to a deficiency in transaction histories, transaction information, or transaction statements pedigree papers.

(12)(13) REFUSAL TO ALLOW INSPECTION; SELLING, PURCHASING, OR TRADING DRUG SAMPLES; FAILURE TO MAINTAIN RECORDS RELATING TO PRESCRIPTION DRUGS.—Any person who violates any of the following provisions commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, or as otherwise provided in this part:

(d) The failure to receive, maintain, or provide invoices and shipping documents, other than pedigree papers, if applicable, related to the distribution of a prescription drug.
FALSE ADVERTISEMENT.—A publisher, radio broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, repackager, wholesale distributor, or seller of the article to which a false advertisement relates, is not liable under subsection (11) (12), subsection (12) (13), or subsection (13) (14) by reason of the dissemination by him or her of such false advertisement, unless he or she has refused, on the request of the department, to furnish to the department the name and post office address of the manufacturer, repackager, wholesale distributor, seller, or advertising agency that asked him or her to disseminate such advertisement.

Section 5. Section 499.006, Florida Statutes, is amended to read:

499.006 Adulterated drug or device.—A drug or device is adulterated, if any of the following apply:

1. If it consists in whole or in part of any filthy, putrid, or decomposed substance;

2. If it has been produced, prepared, packed, or held under conditions whereby it could have been contaminated with filth or rendered injurious to health;

3. If it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, current good manufacturing practices to assure that the drug meets the requirements of this part and that the drug has the identity and strength, and meets the standard of quality and purity, which it purports or is represented to possess;

4. If it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which could render the contents injurious to health;

5. If it is a drug and it bears or contains, for the purpose of coloring only, a color additive that is unsafe within the meaning of the federal act; or, if it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, and it is unsafe within the meaning of the federal act;

6. If it purports to be, or is represented as, a drug the name of which is recognized in the official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. The determination as to strength, quality, or purity must be made in accordance with the tests or methods of assay set forth in such compendium, or, when such tests or methods of assay are absent or inadequate, in accordance with those tests or methods of assay prescribed under authority of the federal act. A drug defined in the official compendium is not adulterated under this subsection merely because it differs from the standard of strength, quality,
or purity set forth for that drug in such compendium if its difference in strength, quality, or purity from such standard is plainly stated on its label;  

(7) If it is not subject to subsection (6) and its strength differs from, or its purity or quality falls below the standard of, that which it purports or is represented to possess;  

(8) If it is a drug:  

(a) With which any substance has been mixed or packed so as to reduce the quality or strength of the drug; or  

(b) For which any substance has been substituted wholly or in part;  

(9) If it is a drug or device for which the expiration date has passed;  

(10) If it is a prescription drug for which the required transaction history, transaction information, or transaction statement pedigree paper is nonexistent, fraudulent, or incomplete under the requirements of this part or applicable rules, or that has been purchased, held, sold, or distributed at any time by a person not authorized under federal or state law to do so; or  

(11) If it is a prescription drug subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a veterinarian to a limited prescription drug veterinary wholesale distributor.

Section 6. Section 499.01, Florida Statutes, is amended to read:

499.01 Permits.—

(1) Before operating, a permit is required for each person and establishment that intends to operate as:  

(a) A prescription drug manufacturer;  

(b) A prescription drug repackager;  

(c) A nonresident prescription drug manufacturer;  

(d) A nonresident prescription drug repackager;  

(e) A prescription drug wholesale distributor;  

(f) An out-of-state prescription drug wholesale distributor;  

(g) A retail pharmacy drug wholesale distributor;  

(h) A restricted prescription drug distributor;  

(i) A complimentary drug distributor;  

(j) A freight forwarder;

CODING: Words stricken are deletions; words underlined are additions.
(k)(j) A veterinary prescription drug retail establishment;
(l)(k) A veterinary prescription drug wholesale distributor;
(m)(l) A limited prescription drug veterinary wholesale distributor;
(n)(m) An over-the-counter drug manufacturer;
(o)(n) A device manufacturer;
(p)(o) A cosmetic manufacturer;
(q)(p) A third party logistics provider; or
(r)(q) A health care clinic establishment.

(2) The following permits are established:

(a) Prescription drug manufacturer permit.—A prescription drug manufacturer permit is required for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.

1. A person that operates an establishment permitted as a prescription drug manufacturer may engage in wholesale distribution of prescription drugs for which the person is the manufacturer manufactured at that establishment and must comply with s. 499.0121 and all other of the provisions of this part, except s. 499.01212, and the rules adopted under this part, except s. 499.01212, which apply to a wholesale distributor. The department shall adopt rules for issuing a virtual prescription drug manufacturer permit to a person who engages in the manufacture of prescription drugs but does not make or take physical possession of any prescription drugs. The rules adopted by the department under this section may exempt virtual manufacturers from certain establishment, security, and storage requirements set forth in s. 499.0121.

2. A prescription drug manufacturer must comply with all appropriate state and federal good manufacturing practices.

3. A blood establishment, as defined in s. 381.06014, operating in a manner consistent with the provisions of 21 C.F.R. parts 211 and 600-640, and manufacturing only the prescription drugs described in s. 499.003(48)(j) or s. 499.003(53)(d) is not required to be permitted as a prescription drug manufacturer under this paragraph or to register products under s. 499.015.

(b) Prescription drug repackager permit.—A prescription drug repackager permit is required for any person that repackages a prescription drug in this state.

1. A person that operates an establishment permitted as a prescription drug repackager may engage in wholesale distribution of prescription drugs repackaged at that establishment and must comply with all of the provisions
of this part and the rules adopted under this part that apply to a prescription drug manufacturer wholesale distributor.

2. A prescription drug repackager must comply with all appropriate state and federal good manufacturing practices.

(c) **Nonresident prescription drug manufacturer permit.**—A nonresident prescription drug manufacturer permit is required for any person that is a manufacturer of prescription drugs, unless permitted as a third party logistics provider, located outside of this state or outside the United States and that engages in the wholesale distribution in this state of such prescription drugs. Each such manufacturer must be permitted by the department and comply with all of the provisions required of a prescription drug manufacturer wholesale distributor under this part, except s. 499.01212. The department shall adopt rules for issuing a virtual nonresident prescription drug manufacturer permit to a person who engages in the manufacture of prescription drugs but does not make or take physical possession of any prescription drugs. The rules adopted by the department under this section may exempt virtual nonresident manufacturers from certain establishment, security, and storage requirements set forth in s. 499.0121.

1. A person that distributes prescription drugs for which the person is not the manufacturer must also obtain an out-of-state prescription drug wholesale distributor permit or third party logistics provider permit pursuant to this section to engage in the wholesale distribution of such prescription drugs when required by this part. This subparagraph does not apply to a manufacturer that distributes prescription drugs only for the manufacturer of the prescription drugs where both manufacturers are affiliates as defined in s. 499.003(30)(e).

2. Any such person must comply with the licensing or permitting requirements of the jurisdiction in which the establishment is located and the federal act, and any prescription drug distributed product wholesaled into this state must comply with this part. If a person intends to import prescription drugs from a foreign country into this state, the nonresident prescription drug manufacturer must provide to the department a list identifying each prescription drug it intends to import and document approval by the United States Food and Drug Administration for such importation.

(d) **Nonresident prescription drug repackager permit.**—A nonresident prescription drug repackager permit is required for any person located outside of this state, but within the United States or its territories, that repackages prescription drugs and engages in the distribution of such prescription drugs into this state.

1. A nonresident prescription drug repackager must comply with all of the provisions of this section and the rules adopted under this section that apply to a prescription drug manufacturer.
2. A nonresident prescription drug repackager must be permitted by the department and comply with all appropriate state and federal good manufacturing practices.

3. A nonresident prescription drug repackager must be registered as a drug establishment with the United States Food and Drug Administration.

(c) Prescription drug wholesale distributor permit.—A prescription drug wholesale distributor permit is required for any person who is a wholesale distributor of prescription drugs and that may engage in the wholesale distributes such distribution of prescription drugs in this state. A prescription drug wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $100,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Professional Regulation Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee’s license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later. The department may adopt rules for issuing a prescription drug wholesale distributor-broker permit to a person who engages in the wholesale distribution of prescription drugs and does not take physical possession of any prescription drugs.

(f) Out-of-state prescription drug wholesale distributor permit.—An out-of-state prescription drug wholesale distributor permit is required for any person that is a wholesale distributor located outside this state, but within the United States or its territories, which engages in the wholesale distribution of prescription drugs into this state and which must be permitted by the department and comply with all the provisions required of a wholesale distributor under this part. An out-of-state prescription drug wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $100,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Professional Regulation Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee’s license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later. The out-of-state prescription drug wholesale distributor must maintain at all times a license or permit to

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engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident. If the state from which the wholesale distributor distributes prescription drugs does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor as required by the federal act.

(g) Retail pharmacy drug wholesale distributor permit.—A retail pharmacy drug wholesale distributor is a retail pharmacy engaged in wholesale distribution of prescription drugs within this state under the following conditions:

1. The pharmacy must obtain a retail pharmacy drug wholesale distributor permit pursuant to this part and the rules adopted under this part.

2. The wholesale distribution activity does not exceed 30 percent of the total annual purchases of prescription drugs. If the wholesale distribution activity exceeds the 30-percent maximum, the pharmacy must obtain a prescription drug wholesale distributor permit.

3. The transfer of prescription drugs that appear in any schedule contained in chapter 893 is subject to chapter 893 and the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.

4. The transfer is between a retail pharmacy and another retail pharmacy, or a Modified Class II institutional pharmacy, or a health care practitioner licensed in this state and authorized by law to dispense or prescribe prescription drugs.

5. All records of sales of prescription drugs subject to this section must be maintained separate and distinct from other records and comply with the recordkeeping requirements of this part.

(h) Restricted prescription drug distributor permit.—

1. A restricted prescription drug distributor permit is required for:

   a. Any person located in this state who engages in the distribution of a prescription drug, which distribution is not considered “wholesale distribution” under s. 499.003(48)(a) 499.003(53)(a).

   b. Any person located in this state who engages in the receipt or distribution of a prescription drug in this state for the purpose of processing its return or its destruction if such person is not the person initiating the return, the prescription drug wholesale supplier of the person initiating the return, or the manufacturer of the drug.

   c. A blood establishment located in this state which collects blood and blood components only from volunteer donors as defined in s. 381.06014 or pursuant to an authorized practitioner’s order for medical treatment or

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therapy and engages in the wholesale distribution of a prescription drug not described in s. 499.003(48)(j) to a health care entity. A mobile blood unit operated by a blood establishment permitted under this sub-subparagraph is not required to be separately permitted. The health care entity receiving a prescription drug distributed under this sub-subparagraph must be licensed as a closed pharmacy or provide health care services at that establishment. The blood establishment must operate in accordance with s. 381.06014 and may distribute only:

(I) Prescription drugs indicated for a bleeding or clotting disorder or anemia;

(II) Blood-collection containers approved under s. 505 of the federal act;

(III) Drugs that are blood derivatives, or a recombinant or synthetic form of a blood derivative;

(IV) Prescription drugs that are identified in rules adopted by the department and that are essential to services performed or provided by blood establishments and authorized for distribution by blood establishments under federal law; or

(V) To the extent authorized by federal law, drugs necessary to collect blood or blood components from volunteer blood donors; for blood establishment personnel to perform therapeutic procedures under the direction and supervision of a licensed physician; and to diagnose, treat, manage, and prevent any reaction of a volunteer blood donor or a patient undergoing a therapeutic procedure performed under the direction and supervision of a licensed physician,

as long as all of the health care services provided by the blood establishment are related to its activities as a registered blood establishment or the health care services consist of collecting, processing, storing, or administering human hematopoietic stem cells or progenitor cells or performing diagnostic testing of specimens if such specimens are tested together with specimens undergoing routine donor testing. The blood establishment may purchase and possess the drugs described in this sub-subparagraph without a health care clinic establishment permit.

2. Storage, handling, and recordkeeping of these distributions by a person required to be permitted as a restricted prescription drug distributor must be in accordance with the requirements for wholesale distributors under s. 499.0121, but not those set forth in s. 499.01212 if the distribution occurs pursuant to sub-subparagraph 1.a. or sub-subparagraph 1.b.

3. A person who applies for a permit as a restricted prescription drug distributor, or for the renewal of such a permit, must provide to the department the information required under s. 499.012.

4. The department may adopt rules regarding the distribution of prescription drugs by hospitals, health care entities, charitable
organizations, other persons not involved in wholesale distribution, and
blood establishments, which rules are necessary for the protection of the
public health, safety, and welfare.

5. A restricted prescription drug distributor permit is not required for
distributions between pharmacies that each hold an active permit under
chapter 465, have a common ownership, and are operating in a freestanding
end-stage renal dialysis clinic, if such distributions are made to meet the
immediate emergency medical needs of specifically identified patients and
do not occur with such frequency as to amount to the regular and systematic
supplying of that drug between the pharmacies. The department shall adopt
rules establishing when the distribution of a prescription drug under this
subparagraph amounts to the regular and systematic supplying of that drug.

(i) Complimentary drug distributor permit.—A complimentary drug
distributor permit is required for any person that engages in the distribution
of a complimentary drug, subject to the requirements of s. 499.028.

(j) Freight forwarder permit.—A freight forwarder permit is required
for any person that engages in the distribution of a prescription drug as a
freight forwarder unless the person is a common carrier. The storage,
handling, and recordkeeping of such distributions must comply with the
requirements for wholesale distributors under s. 499.0121, but not those set
forth in s. 499.01212. A freight forwarder must provide the source of the
prescription drugs with a validated airway bill, bill of lading, or other
appropriate documentation to evidence the exportation of the product.

(k) Veterinary prescription drug retail establishment permit.—A ve-
terinary prescription drug retail establishment permit is required for any
person that sells veterinary prescription drugs to the public but does not
include a pharmacy licensed under chapter 465.

1. The sale to the public must be based on a valid written order from a
veterinarian licensed in this state who has a valid client-veterinarian
relationship with the purchaser's animal.

2. Veterinary prescription drugs may not be sold in excess of the amount
clearly indicated on the order or beyond the date indicated on the order.

3. An order may not be valid for more than 1 year.

4. A veterinary prescription drug retail establishment may not purchase,
sell, trade, or possess human prescription drugs or any controlled substance
as defined in chapter 893.

5. A veterinary prescription drug retail establishment must sell a
veterinary prescription drug in the original, sealed manufacturer's contain-
er with all labeling intact and legible. The department may adopt by rule
additional labeling requirements for the sale of a veterinary prescription
drug.
6. A veterinary prescription drug retail establishment must comply with all of the wholesale distribution requirements of s. 499.0121.

7. Prescription drugs sold by a veterinary prescription drug retail establishment pursuant to a practitioner's order may not be returned into the retail establishment's inventory.

   (l)(k) Veterinary prescription drug wholesale distributor permit.—A veterinary prescription drug wholesale distributor permit is required for any person that engages in the distribution of veterinary prescription drugs in or into this state. A veterinary prescription drug wholesale distributor that also distributes prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which it did not manufacture must obtain a permit as a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, or a limited prescription drug veterinary wholesale distributor in lieu of the veterinary prescription drug wholesale distributor permit. A veterinary prescription drug wholesale distributor must comply with the requirements for wholesale distributors under s. 499.0121, but not those set forth in s. 499.01212.

   (m)(l) Limited prescription drug veterinary wholesale distributor permit. Unless engaging in the activities of and permitted as a prescription drug manufacturer, nonresident prescription drug manufacturer, prescription drug wholesale distributor, or out-of-state prescription drug wholesale distributor, a limited prescription drug veterinary wholesale distributor permit is required for any person that engages in the distribution in or into this state of veterinary prescription drugs and prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act under the following conditions:

   1. The person is engaged in the business of wholesaling prescription and veterinary prescription drugs to persons:
      a. Licensed as veterinarians practicing on a full-time basis;
      b. Regularly and lawfully engaged in instruction in veterinary medicine;
      c. Regularly and lawfully engaged in law enforcement activities;
      d. For use in research not involving clinical use; or
      e. For use in chemical analysis or physical testing or for purposes of instruction in law enforcement activities, research, or testing.

   2. No more than 30 percent of total annual prescription drug sales may be prescription drugs approved for human use which are subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.

   3. The person does not distribute in any jurisdiction prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug,
and Cosmetic Act to any person who is authorized to sell, distribute, purchase, trade, or use these drugs on or for humans.

4. A limited prescription drug veterinary wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $20,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Professional Regulation Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee’s license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later.

5. A limited prescription drug veterinary wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident.

6. A limited prescription drug veterinary wholesale distributor must comply with the requirements for wholesale distributors under ss. 499.0121 and 499.01212, except that a limited prescription drug veterinary wholesale distributor is not required to provide a pedigree paper as required by s. 499.01212 upon the wholesale distribution of a prescription drug to a veterinarian.

7. A limited prescription drug veterinary wholesale distributor may not return to inventory for subsequent wholesale distribution any prescription drug subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a veterinarian.

8. A limited prescription drug veterinary wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed to engage in the wholesale distribution of prescription drugs in its state of residence to a licensed limited prescription drug veterinary wholesale distributor in this state if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of ss. 499.0121(6) and 499.01212 must be followed for this transaction.

(n)(m) Over-the-counter drug manufacturer permit.—An over-the-counter drug manufacturer permit is required for any person that engages in the manufacture or repackaging of an over-the-counter drug.

1. An over-the-counter drug manufacturer may not possess or purchase prescription drugs.

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2. A pharmacy is exempt from obtaining an over-the-counter drug manufacturer permit if it is operating in compliance with pharmacy practice standards as defined in chapter 465 and the rules adopted under that chapter.

3. An over-the-counter drug manufacturer must comply with all appropriate state and federal good manufacturing practices.

(o) Device manufacturer permit.—

1. A device manufacturer permit is required for any person that engages in the manufacture, repackaging, or assembly of medical devices for human use in this state, except that a permit is not required if:

a. The person is engaged only in manufacturing, repackaging, or assembling a medical device pursuant to a practitioner’s order for a specific patient; or

b. The person does not manufacture, repackage, or assemble any medical devices or components for such devices, except those devices or components which are exempt from registration pursuant to s. 499.015(8).

2. A manufacturer or repackager of medical devices in this state must comply with all appropriate state and federal good manufacturing practices and quality system rules.

3. The department shall adopt rules related to storage, handling, and recordkeeping requirements for manufacturers of medical devices for human use.

(p) Cosmetic manufacturer permit.—A cosmetic manufacturer permit is required for any person that manufactures or repackages cosmetics in this state. A person that only labels or changes the labeling of a cosmetic but does not open the container sealed by the manufacturer of the product is exempt from obtaining a permit under this paragraph.

(q) Third party logistics provider permit.—A third party logistics provider permit is required for any person that contracts with a prescription drug wholesale distributor or prescription drug manufacturer to provide warehousing, distribution, or other logistics services on behalf of a manufacturer, or wholesale distributor, or dispenser, but who does not take title to the prescription drug or have responsibility to direct the sale or disposition of the prescription drug. A third party logistics provider located outside of this state, must be licensed in the state or territory from which the prescription drug is distributed by the third party logistics provider. If the state or territory from which the third party logistics provider originates does not require a license to operate as a third party logistics provider, the third party logistics provider must be licensed as a third party logistics provider as required by the federal act. Each third party logistics provider permittee shall comply with the requirements for wholesale distributors under ss. 499.0121 and 499.01212, with the exception of those wholesale

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distributions described in s. 499.01212(3)(a), and other rules that the department requires.

**(r)(q)** Health care clinic establishment permit. — Effective January 1, 2009, a health care clinic establishment permit is required for the purchase of a prescription drug by a place of business at one general physical location that provides health care or veterinary services, which is owned and operated by a business entity that has been issued a federal employer tax identification number. For the purpose of this paragraph, the term “qualifying practitioner” means a licensed health care practitioner defined in s. 456.001, or a veterinarian licensed under chapter 474, who is authorized under the appropriate practice act to prescribe and administer a prescription drug.

1. An establishment must provide, as part of the application required under s. 499.012, designation of a qualifying practitioner who will be responsible for complying with all legal and regulatory requirements related to the purchase, recordkeeping, storage, and handling of the prescription drugs. In addition, the designated qualifying practitioner shall be the practitioner whose name, establishment address, and license number is used on all distribution documents for prescription drugs purchased or returned by the health care clinic establishment. Upon initial appointment of a qualifying practitioner, the qualifying practitioner and the health care clinic establishment shall notify the department on a form furnished by the department within 10 days after such employment. In addition, the qualifying practitioner and health care clinic establishment shall notify the department within 10 days after any subsequent change.

2. The health care clinic establishment must employ a qualifying practitioner at each establishment.

3. In addition to the remedies and penalties provided in this part, a violation of this chapter by the health care clinic establishment or qualifying practitioner constitutes grounds for discipline of the qualifying practitioner by the appropriate regulatory board.

4. The purchase of prescription drugs by the health care clinic establishment is prohibited during any period of time when the establishment does not comply with this paragraph.

5. A health care clinic establishment permit is not a pharmacy permit or otherwise subject to chapter 465. A health care clinic establishment that meets the criteria of a modified Class II institutional pharmacy under s. 465.019 is not eligible to be permitted under this paragraph.

6. This paragraph does not apply to the purchase of a prescription drug by a licensed practitioner under his or her license.

(3) A nonresident prescription drug manufacturer permit is not required for a manufacturer to distribute a prescription drug active pharmaceutical
ingredient that it manufactures to a prescription drug manufacturer permitted in this state in limited quantities intended for research and development and not for resale or human use other than lawful clinical trials and biostudies authorized and regulated by federal law. A manufacturer claiming to be exempt from the permit requirements of this subsection and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212. The prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall maintain on file a record of the FDA registration number; if available, the out-of-state license, permit, or registration number; and, if available, a copy of the most current FDA inspection report, for all manufacturers from whom they purchase active pharmaceutical ingredients under this section. The department shall define the term “limited quantities” by rule, and may include the allowable number of transactions within a given period of time and the amount of prescription drugs distributed into the state for purposes of this exemption. The failure to comply with the requirements of this subsection, or rules adopted by the department to administer this subsection, for the purchase of prescription drug active pharmaceutical ingredients is a violation of s. 499.005(14), and a knowing failure is a violation of s. 499.0051(3) 499.0051(4).

(a) The immediate package or container of a prescription drug active pharmaceutical ingredient distributed into the state that is intended for research and development under this subsection shall bear a label prominently displaying the statement: “Caution: Research and Development Only—Not for Manufacturing, Compounding, or Resale.”

(b) A prescription drug manufacturer that obtains a prescription drug active pharmaceutical ingredient under this subsection for use in clinical trials and or biostudies authorized and regulated by federal law must create and maintain records detailing the specific clinical trials or biostudies for which the prescription drug active pharmaceutical ingredient was obtained.

(4)(a) A permit issued under this part is not required to distribute a prescription drug active pharmaceutical ingredient from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for use by the recipient in preparing, deriving, processing, producing, or fabricating a prescription drug finished dosage form at the establishment in this state where the product is received under an approved and otherwise valid New Drug Approval Application, Abbreviated New Drug Application, New Animal Drug Application, or Therapeutic Biologic Application, provided that the application, active pharmaceutical ingredient, or finished dosage form has not been withdrawn or removed from the market in this country for public health reasons.

1. Any distributor claiming exemption from permitting requirements pursuant to this paragraph shall maintain a license, permit, or registration to engage in the wholesale distribution of prescription drugs under the laws
of the state from which the product is distributed. If the state from which the prescription drugs are distributed does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor as required by the federal act.

2. Any distributor claiming exemption from permitting requirements pursuant to this paragraph and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212.

(b) A permit issued under this part is not required to distribute limited quantities of a prescription drug that has not been repackaged from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for research and development or to a holder of a letter of exemption issued by the department under s. 499.03(4) for research, teaching, or testing. The department shall define “limited quantities” by rule and may include the allowable number of transactions within a given period of time and the amounts of prescription drugs distributed into the state for purposes of this exemption.

1. Any distributor claiming exemption from permitting requirements pursuant to this paragraph shall maintain a license, permit, or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed. If the state from which the prescription drugs are distributed does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor as required by the federal act.

2. All purchasers and recipients of any prescription drugs distributed pursuant to this paragraph shall ensure that the products are not resold or used, directly or indirectly, on humans except in lawful clinical trials and biostudies authorized and regulated by federal law.

3. Any distributor claiming exemption from permitting requirements pursuant to this paragraph, and the purchaser and recipient of the prescription drug, shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212.

4. The immediate package or container of any active pharmaceutical ingredient distributed into the state that is intended for teaching, testing, research, and development shall bear a label prominently displaying the statement: “Caution: Research, Teaching, or Testing Only – Not for Manufacturing, Compounding, or Resale.”

(c) An out-of-state prescription drug wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed as a prescription drug wholesale distributor in its state of residence to a licensed prescription drug
wholesale distributor in this state, if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of s. ss. 499.0121(6) and 499.01212 must be followed for such transactions.

(d) Persons receiving prescription drugs from a source claimed to be exempt from permitting requirements under this subsection shall maintain on file:

1. A record of the FDA establishment registration number, if any;

2. The resident state or federal license, registration, or permit that authorizes the source to distribute prescription drugs; drug wholesale distribution license, permit, or registration number; and

3. A copy of the most recent resident state or FDA inspection report, for all distributors and establishments from whom they purchase or receive prescription drugs under this subsection.

(e) All persons claiming exemption from permitting requirements pursuant to this subsection who engage in the distribution of prescription drugs within or into the state are subject to this part, including ss. 499.005 and 499.0051, and shall make available, within 48 hours, to the department on request all records related to any prescription drugs distributed under this subsection, including those records described in s. 499.051(4), regardless of the location where the records are stored.

(f) A person purchasing and receiving a prescription drug from a person claimed to be exempt from licensing requirements pursuant to this subsection shall report to the department in writing within 14 days after receiving any product that is misbranded or adulterated or that fails to meet minimum standards set forth in the official compendium or state or federal good manufacturing practices for identity, purity, potency, or sterility, regardless of whether the product is thereafter rehabilitated, quarantined, returned, or destroyed.

(g) The department may adopt rules to administer this subsection which are necessary for the protection of the public health, safety, and welfare. Failure to comply with the requirements of this subsection, or rules adopted by the department to administer this subsection, is a violation of s. 499.005(14), and a knowing failure is a violation of s. 499.0051(3).

(h) This subsection does not relieve any person from any requirement prescribed by law with respect to controlled substances as defined in the applicable federal and state laws.

(5) A prescription drug repackager permit issued under this part is not required for a restricted prescription drug distributor permitholder that is a health care entity to repackage prescription drugs in this state for its own
use or for distribution to hospitals or other health care entities in the state for their own use, pursuant to s. 499.003(48)(a)3., 499.003(53)(a)3., if:

(a) The prescription drug distributor notifies the department, in writing, of its intention to engage in repackaging under this exemption, 30 days before engaging in the repackaging of prescription drugs at the permitted establishment;

(b) The prescription drug distributor is under common control with the hospitals or other health care entities to which the prescription drug distributor is distributing prescription drugs. As used in this paragraph, “common control” means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise;

(c) The prescription drug distributor repackages the prescription drugs in accordance with current state and federal good manufacturing practices; and

(d) The prescription drug distributor labels the prescription drug it repackages in accordance with state and federal laws and rules.

The prescription drug distributor is exempt from the product registration requirements of s. 499.015 with regard to the prescription drugs that it repackages and distributes under this subsection. A prescription drug distributor that repackages and distributes prescription drugs under this subsection to a not-for-profit rural hospital, as defined in s. 395.602, is not required to comply with paragraph (c) or paragraph (d), but must provide to each health care entity for which it repackages, for each prescription drug that is repackaged and distributed, the information required by department rule for labeling prescription drugs. The department shall adopt rules to ensure the safety and integrity of prescription drugs repackaged and distributed under this subsection, including rules regarding prescription drug manufacturing and labeling requirements.

Section 7. Section 499.012, Florida Statutes, is amended to read:

499.012 Permit application requirements.—

(1)(a) A permit issued pursuant to this part may be issued only to a natural person who is at least 18 years of age or to an applicant that is not a natural person if each person who, directly or indirectly, manages, controls, or oversees the operation of that applicant is at least 18 years of age.

(b) An establishment that is a place of residence may not receive a permit and may not operate under this part.

(c) A person that applies for or renews a permit to manufacture or distribute prescription drugs may not use a name identical to the name used by any other establishment or licensed person authorized to purchase prescription drugs in this state, except that a restricted drug distributor...
permit issued to a health care entity will be issued in the name in which the
institutional pharmacy permit is issued and a retail pharmacy drug
wholesale distributor will be issued a permit in the name of its retail
pharmacy permit.

(d) A permit for a prescription drug manufacturer, prescription drug
repackager, prescription drug wholesale distributor, limited prescription
drug veterinary wholesale distributor, or retail pharmacy drug wholesale
distributor may not be issued to the address of a health care entity or to a
pharmacy licensed under chapter 465, except as provided in this paragraph.
The department may issue a prescription drug manufacturer permit to an
applicant at the same address as a licensed nuclear pharmacy, which is a
health care entity, even if the nuclear pharmacy holds a special sterile
compounding permit under chapter 465, for the purpose of manufacturing
prescription drugs used in positron emission tomography or other radio-
pharmaceuticals, as listed in a rule adopted by the department pursuant to
this paragraph. The purpose of this exemption is to assure availability of
state-of-the-art pharmaceuticals that would pose a significant danger to the
public health if manufactured at a separate establishment address from the
nuclear pharmacy from which the prescription drugs are dispensed. The
department may also issue a retail pharmacy drug wholesale distributor
permit to the address of a community pharmacy licensed under chapter 465,
even if the community pharmacy holds a special sterile compounding permit
under chapter 465, as long as the community pharmacy which does not meet
the definition of a closed pharmacy in s. 499.003.

(e) A county or municipality may not issue an occupational license for
any licensing period beginning on or after October 1, 2003, for any
establishment that requires a permit pursuant to this part, unless the
establishment exhibits a current permit issued by the department for the
establishment. Upon presentation of the requisite permit issued by the
department, an occupational license may be issued by the municipality or
county in which application is made. The department shall furnish to local
agencies responsible for issuing occupational licenses a current list of all
establishments licensed pursuant to this part.

(2) Notwithstanding subsection (6), a permitted person in good standing
may change the type of permit issued to that person by completing a new
application for the requested permit, paying the amount of the difference in
the permit fees if the fee for the new permit is more than the fee for the
original permit, and meeting the applicable permitting conditions for the
new permit type. The new permit expires on the expiration date of the
original permit being changed; however, a new permit for a prescription
drug wholesale distributor, an out-of-state prescription drug wholesale
distributor, or a retail pharmacy drug wholesale distributor shall expire on
the expiration date of the original permit or 1 year after the date of issuance
of the new permit, whichever is earlier. A refund may not be issued if the fee
for the new permit is less than the fee that was paid for the original permit.
(3)(a) A written application for a permit or to renew a permit must be filed with the department on forms furnished by the department. The department shall establish, by rule, the form and content of the application to obtain or renew a permit. The applicant must submit to the department with the application a statement that swears or affirms that the information is true and correct.

(b) Upon a determination that 2 years have elapsed since the department notified an applicant for permit, certification, or product registration of a deficiency in the application and that the applicant has failed to cure the deficiency, the application shall expire. The determination regarding the 2-year lapse of time shall be based on documentation that the department notified the applicant of the deficiency in accordance with s. 120.60.

(c) Information submitted by an applicant on an application required pursuant to this subsection which is a trade secret, as defined in s. 812.081, shall be maintained by the department as trade secret information pursuant to s. 499.051(7).

(4)(a) Except for a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor, an application for a permit must include:

1. The name, full business address, and telephone number of the applicant;
2. All trade or business names used by the applicant;
3. The address, telephone numbers, and the names of contact persons for each facility used by the applicant for the storage, handling, and distribution of prescription drugs;
4. The type of ownership or operation, such as a partnership, corporation, or sole proprietorship; and
5. The names of the owner and the operator of the establishment, including:
   a. If an individual, the name of the individual;
   b. If a partnership, the name of each partner and the name of the partnership;
   c. If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation;
   d. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;
e. If a limited liability company, the name of each member, the name of each manager, the name of the limited liability company, and the name of the state in which the limited liability company was organized; and

f. Any other relevant information that the department requires.

(b) Upon approval of the application by the department and payment of the required fee, the department shall issue a permit to the applicant, if the applicant meets the requirements of this part and rules adopted under this part.

(c) Any change in information required under paragraph (a) must be submitted to the department before the change occurs.

(d) The department shall consider, at a minimum, the following factors in reviewing the qualifications of persons to be permitted under this part:

1. The applicant’s having been found guilty, regardless of adjudication, in a court of this state or other jurisdiction, of a violation of a law that directly relates to a drug, device, or cosmetic. A plea of nolo contendere constitutes a finding of guilt for purposes of this subparagraph.

2. The applicant’s having been disciplined by a regulatory agency in any state for any offense that would constitute a violation of this part.

3. Any felony conviction of the applicant under a federal, state, or local law;

4. The applicant’s past experience in manufacturing or distributing drugs, devices, or cosmetics;

5. The furnishing by the applicant of false or fraudulent material in any application made in connection with manufacturing or distributing drugs, devices, or cosmetics;

6. Suspension or revocation by a federal, state, or local government of any permit currently or previously held by the applicant for the manufacture or distribution of any drugs, devices, or cosmetics;

7. Compliance with permitting requirements under any previously granted permits;

8. Compliance with requirements to maintain or make available to the state permitting authority or to federal, state, or local law enforcement officials those records required under this section; and

9. Any other factors or qualifications the department considers relevant to and consistent with the public health and safety.

(5) Except for a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor:

CODING: Words struck are deletions; words underlined are additions.
(a) The department shall adopt rules for the biennial renewal of permits; however, the department may issue up to a 4-year permit to selected permittees notwithstanding any other provision of law. Fees for such renewal may not exceed the fee caps set forth in s. 499.041 on an annualized basis as authorized by law.

(b) The department shall renew a permit upon receipt of the renewal application and renewal fee if the applicant meets the requirements established under this part and the rules adopted under this part.

(c) At least 90 days before the expiration date of a permit, the department shall forward a permit renewal notification to the permittee at the mailing address of the permitted establishment on file with the department. The permit renewal notification must state conspicuously the date on which the permit for the establishment will expire and that the establishment may not operate unless the permit for the establishment is renewed timely. A permit, unless sooner suspended or revoked, automatically expires 2 years after the last day of the anniversary month in which the permit was originally issued.

(d) A permit issued under this part may be renewed by making application for renewal on forms furnished by the department and paying the appropriate fees.

1. If a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor renewal application and fee are submitted and postmarked later than 45 days before the expiration date of the permit, the permit may be renewed only upon payment of a late renewal fee of $100, plus the required renewal fee.

2. If any other a renewal application and fee are submitted and postmarked after the expiration date of the permit, the permit may be renewed only upon payment of a late renewal delinquent fee of $100, plus the required renewal fee, not later than 60 days after the expiration date.

3. A permittee who submits a renewal application in accordance with this paragraph may continue to operate under its permit, unless the permit is suspended or revoked, until final disposition of the renewal application.

4.(d) Failure to renew a permit in accordance with this section precludes any future renewal of that permit. If a permit issued pursuant to this part has expired and cannot be renewed, before an establishment may engage in activities that require a permit under this part, the establishment must submit an application for a new permit, pay the applicable application fee, the initial permit fee, and all applicable penalties, and be issued a new permit by the department.

5. A permit issued by the department is nontransferable. Each permit is valid only for the person or governmental unit to which it is issued and is not subject to sale, assignment, or other transfer, voluntarily or involuntarily;
nor is a permit valid for any establishment other than the establishment for which it was originally issued.

(a) A person permitted under this part must notify the department before making a change of address. The department shall set a change of location fee not to exceed $100.

(b) 1. An application for a new permit is required when a majority of the ownership or controlling interest of a permitted establishment is transferred or assigned or when a lessee agrees to undertake or provide services to the extent that legal liability for operation of the establishment will rest with the lessee. The application for the new permit must be made before the date of the sale, transfer, assignment, or lease.

2. A permittee that is authorized to distribute prescription drugs may transfer such drugs to the new owner or lessee under subparagraph 1. only after the new owner or lessee has been approved for a permit to distribute prescription drugs.

(c) If an establishment permitted under this part closes, the owner must notify the department in writing before the effective date of closure and must:

1. Return the permit to the department;

2. If the permittee is authorized to distribute prescription drugs, indicate the disposition of such drugs, including the name, address, and inventory, and provide the name and address of a person to contact regarding access to records that are required to be maintained under this part. Transfer of ownership of prescription drugs may be made only to persons authorized to possess prescription drugs under this part.

The department may revoke the permit of any person that fails to comply with the requirements of this subsection.

(7) A permit must be posted in a conspicuous place on the licensed premises.

(8) An application for a permit or to renew a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor submitted to the department must include:

(a) The name, full business address, and telephone number of the applicant.

(b) All trade or business names used by the applicant.

(c) The address, telephone numbers, and the names of contact persons for each facility used by the applicant for the storage, handling, and distribution of prescription drugs.
(d) The type of ownership or operation, such as a partnership, corporation, or sole proprietorship.

(e) The names of the owner and the operator of the establishment, including:

1. If an individual, the name of the individual.

2. If a partnership, the name of each partner and the name of the partnership.

3. If a corporation:
   a. The name, address, and title of each corporate officer and director.
   b. The name and address of the corporation, resident agent of the corporation, the resident agent’s address, and the corporation’s state of incorporation.
   c. The name and address of each shareholder of the corporation that owns 5 percent or more of the outstanding stock of the corporation.

4. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

5. If a limited liability company:
   a. The name and address of each member.
   b. The name and address of each manager.
   c. The name and address of the limited liability company, the resident agent of the limited liability company, and the name of the state in which the limited liability company was organized.

(f) If applicable, the name and address of each affiliate of member of the affiliated group of which the applicant is a member.

(g)1. The applicant’s gross annual receipts attributable to prescription drug wholesale distribution activities for the previous tax year. For an application for a new permit, the estimated annual dollar volume of prescription drug sales of the applicant, the estimated annual percentage of the applicant’s total company sales that are prescription drugs, the applicant’s estimated annual total dollar volume of purchases of prescription drugs, and the applicant’s estimated annual total dollar volume of prescription drug purchases directly from manufacturers.

2. For an application to renew a permit, the total dollar volume of prescription drug sales in the previous year, the total dollar volume of prescription drug sales made in the previous 6 months, the percentage of total company sales that were prescription drugs in the previous year, the total dollar volume of purchases of prescription drugs in the previous year,
and the total dollar volume of prescription drug purchases directly from manufacturers in the previous year.

Such portions of the information required pursuant to this paragraph which are a trade secret, as defined in s. 812.081, shall be maintained by the department as trade secret information is required to be maintained under s. 499.051.

(h) The tax year of the applicant.

(i) A copy of the deed for the property on which applicant’s establishment is located, if the establishment is owned by the applicant, or a copy of the applicant’s lease for the property on which applicant’s establishment is located that has an original term of not less than 1 calendar year, if the establishment is not owned by the applicant.

(j) A list of all licenses and permits issued to the applicant by any other state which authorize the applicant to purchase or possess prescription drugs.

(k) The name of the manager of the establishment that is applying for the permit or to renew the permit, the next four highest ranking employees responsible for prescription drug wholesale operations for the establishment, and the name of all affiliated parties for the establishment, together with the personal information statement and fingerprints required pursuant to subsection (9) for each of such persons.

(l) The name of each of the applicant’s designated representatives as required by subsection (15) (16), together with the personal information statement and fingerprints required pursuant to subsection (9) for each such person.

(m) Evidence of a surety bond in this state or any other state in the United States in the amount of $100,000. If the annual gross receipts of the applicant’s previous tax year is $10 million or less, evidence of a surety bond in the amount of $25,000. The specific language of the surety bond must include the State of Florida as a beneficiary, payable to the Professional Regulation Trust Fund. In lieu of the surety bond, the applicant may provide other equivalent security such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, which includes the State of Florida as a beneficiary, payable to the Professional Regulation Trust Fund. The purpose of the bond or other security is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee’s license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including
any appeal, whichever occurs later. For an applicant that is a secondary wholesale distributor, each of the following:

1. A personal background information statement containing the background information and fingerprints required pursuant to subsection (9) for each person named in the applicant’s response to paragraphs (k) and (l) and for each affiliated party of the applicant.

2. If any of the five largest shareholders of the corporation seeking the permit is a corporation, the name, address, and title of each corporate officer and director of each such corporation; the name and address of such corporation; the name of such corporation’s resident agent, such corporation’s resident agent’s address, and such corporation’s state of its incorporation; and the name and address of each shareholder of such corporation that owns 5 percent or more of the stock of such corporation.

3. The name and address of all financial institutions in which the applicant has an account which is used to pay for the operation of the establishment or to pay for drugs purchased for the establishment, together with the names of all persons that are authorized signatories on such accounts. The portions of the information required pursuant to this subparagraph which are a trade secret, as defined in s. 812.081, shall be maintained by the department as trade secret information is required to be maintained under s. 499.051.

4. The sources of all funds and the amounts of such funds used to purchase or finance purchases of prescription drugs or to finance the premises on which the establishment is to be located.

5. If any of the funds identified in subparagraph 4. were borrowed, copies of all promissory notes or loans used to obtain such funds.

(n) For establishments used in wholesale distribution, proof of an inspection conducted by the department, the United States Food and Drug Administration, or another governmental entity charged with the regulation of good manufacturing practices related to wholesale distribution of prescription drugs, within timeframes set forth by the department in departmental rules, which demonstrates substantial compliance with current good manufacturing practices applicable to wholesale distribution of prescription drugs. The department may recognize another state’s inspection of a wholesale distributor located in that state if such state’s laws are deemed to be substantially equivalent to the law of this state by the department. The department may accept an inspection by a third-party accreditation or inspection service which meets the criteria set forth in department rule.

(o)(n) Any other relevant information that the department requires, including, but not limited to, any information related to whether the applicant satisfies the definition of a primary wholesale distributor or a secondary wholesale distributor.

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Documentation of the credentialing policies and procedures required by s. 499.0121(15).

(9)(a) Each person required by subsection (8) or subsection (15) to provide a personal information statement and fingerprints shall provide the following information to the department on forms prescribed by the department:

1. The person’s places of residence for the past 7 years.

2. The person’s date and place of birth.

3. The person’s occupations, positions of employment, and offices held during the past 7 years.

4. The principal business and address of any business, corporation, or other organization in which each such office of the person was held or in which each such occupation or position of employment was carried on.

5. Whether the person has been, during the past 7 years, the subject of any proceeding for the revocation of any license and, if so, the nature of the proceeding and the disposition of the proceeding.

6. Whether, during the past 7 years, the person has been enjoined, temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control, or distribution of prescription drugs, together with details concerning any such event.

7. A description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past 7 years, which manufactured, administered, prescribed, distributed, or stored pharmaceutical products and any lawsuits in which such businesses were named as a party.

8. A description of any felony criminal offense of which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendere. A criminal offense committed in another jurisdiction which would have been a felony in this state must be reported. If the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of that criminal offense, the applicant must, within 15 days after the disposition of the appeal, submit to the department a copy of the final written order of disposition.

9. A photograph of the person taken in the previous 180 days.

10. A set of fingerprints for the person on a form and under procedures specified by the department, together with payment of an amount equal to
the costs incurred by the department for the criminal record check of the person.

11. The name, address, occupation, and date and place of birth for each member of the person’s immediate family who is 18 years of age or older. As used in this subparagraph, the term “member of the person’s immediate family” includes the person’s spouse, children, parents, siblings, the spouses of the person’s children, and the spouses of the person’s siblings.

12. Any other relevant information that the department requires.

(b) The information required pursuant to paragraph (a) shall be provided under oath.

(c) The department shall submit the fingerprints provided by a person for initial licensure to the Department of Law Enforcement for a statewide criminal record check and for forwarding to the Federal Bureau of Investigation for a national criminal record check of the person. The department shall submit the fingerprints provided by a person as a part of a renewal application to the Department of Law Enforcement for a statewide criminal record check and for forwarding to the Federal Bureau of Investigation for a national criminal record check of the person. For the initial renewal of a permit after January 1, 2004; for any subsequent renewal of a permit, the department shall submit the required information for a statewide and national criminal record check of the person. Any person who as a part of an initial permit application or initial permit renewal after January 1, 2004, submits to the department a set of fingerprints required for the criminal record check required in this paragraph are shall not be required to provide a subsequent set of fingerprints for a criminal record check to the department, if the person has undergone a criminal record check as a condition of the issuance of an initial permit or the initial renewal of a permit of an applicant after January 1, 2004. The department is authorized to contract with private vendors, or enter into interagency agreements, to collect electronic fingerprints where fingerprints are required for registration, certification, or the licensure process or where criminal history record checks are required.

(d) For purposes of applying for renewal of a permit under subsection (8) or certification under subsection (16), a person may submit the following in lieu of satisfying the requirements of paragraphs (a), (b), and (c):

1. A photograph of the individual taken within 180 days; and

2. A copy of the personal information statement form most recently submitted to the department and a certification under oath, on a form specified by the department, that the individual has reviewed the previously submitted personal information statement form and that the information contained therein remains unchanged.

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(10) The department may deny an application for a permit or refuse to renew a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor if:

(a) The applicant has not met the requirements for the permit.

(b) The management, officers, or directors of the applicant or any affiliated party are found by the department to be incompetent or untrustworthy.

(c) The applicant is so lacking in experience in managing a wholesale distributor as to make the issuance of the proposed permit hazardous to the public health.

(d) The applicant is so lacking in experience in managing a wholesale distributor as to jeopardize the reasonable promise of successful operation of the wholesale distributor.

(e) The applicant is lacking in experience in the distribution of prescription drugs.

(f) The applicant’s past experience in manufacturing or distributing prescription drugs indicates that the applicant poses a public health risk.

(g) The applicant is affiliated directly or indirectly through ownership, control, or other business relations, with any person or persons whose business operations are or have been detrimental to the public health.

(h) The applicant, or any affiliated party, has been found guilty of or has pleaded guilty or nolo contendere to any felony or crime punishable by imprisonment for 1 year or more under the laws of the United States, any state, or any other country, regardless of whether adjudication of guilt was withheld.

(i) The applicant or any affiliated party has been charged with a felony in a state or federal court and the disposition of that charge is pending during the application review or renewal review period.

(j) The applicant has furnished false or fraudulent information or material in any application made in this state or any other state in connection with obtaining a permit or license to manufacture or distribute drugs, devices, or cosmetics.

(k) That a federal, state, or local government permit currently or previously held by the applicant, or any affiliated party, for the manufacture or distribution of any drugs, devices, or cosmetics has been disciplined, suspended, or revoked and has not been reinstated.

(l) The applicant does not possess the financial or physical resources to operate in compliance with the permit being sought, this chapter, and the rules adopted under this chapter.

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(m) The applicant or any affiliated party receives, directly or indirectly, financial support and assistance from a person who was an affiliated party of a permittee whose permit was subject to discipline or was suspended or revoked, other than through the ownership of stock in a publicly traded company or a mutual fund.

(n) The applicant or any affiliated party receives, directly or indirectly, financial support and assistance from a person who has been found guilty of any violation of this part or chapter 465, chapter 501, or chapter 893, any rules adopted under this part or those chapters, any federal or state drug law, or any felony where the underlying facts related to drugs, regardless of whether the person has been pardoned, had her or his civil rights restored, or had adjudication withheld, other than through the ownership of stock in a publicly traded company or a mutual fund.

(o) The applicant for renewal of a permit under s. 499.01(2)(e) or (f) 499.01(2)(d) or (e) has not actively engaged in the wholesale distribution of prescription drugs, as demonstrated by the regular and systematic distribution of prescription drugs throughout the year as evidenced by not fewer than 12 wholesale distributions in the previous year and not fewer than three wholesale distributions in the previous 6 months.

(p) Information obtained in response to s. 499.01(2)(e) or (f) 499.01(2)(d) or (e) demonstrates it would not be in the best interest of the public health, safety, and welfare to issue a permit.

(q) The applicant does not possess the financial standing and business experience for the successful operation of the applicant.

(r) The applicant or any affiliated party has failed to comply with the requirements for manufacturing or distributing prescription drugs under this part, similar federal laws, similar laws in other states, or the rules adopted under such laws.

(11) Upon approval of the application by the department and payment of the required fee, the department shall issue or renew a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor permit to the applicant.

(12) For a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor:

(a) The department shall adopt rules for the annual renewal of permits. At least 90 days before the expiration of a permit, the department shall forward a permit renewal notification and renewal application to the prescription drug wholesale distributor or out of state prescription drug wholesale distributor at the mailing address of the permitted establishment on file with the department. The permit renewal notification must state conspicuously the date on which the permit for the establishment will expire.

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and that the establishment may not operate unless the permit for the establishment is renewed timely.

(b) A permit, unless sooner suspended or revoked, automatically expires 1 year after the last day of the anniversary month in which the permit was originally issued. A permit may be renewed by making application for renewal on forms furnished by the department and paying the appropriate fees. If a renewal application and fee are submitted and postmarked after 45 days prior to the expiration date of the permit, the permit may be renewed only upon payment of a late renewal fee of $100, plus the required renewal fee. A permittee that has submitted a renewal application in accordance with this paragraph may continue to operate under its permit, unless the permit is suspended or revoked, until final disposition of the renewal application.

(c) Failure to renew a permit in accordance with this section precludes any future renewal of that permit. If a permit issued pursuant to this section has expired and cannot be renewed, before an establishment may engage in activities that require a permit under this part, the establishment must submit an application for a new permit; pay the applicable application fee, initial permit fee, and all applicable penalties; and be issued a new permit by the department.

(12)(13) A person that engages in wholesale distribution of prescription drugs in this state must have a wholesale distributor’s permit issued by the department, except as noted in this section. Each establishment must be separately permitted except as noted in this subsection.

(a) A separate establishment permit is not required when a permitted prescription drug wholesale distributor consigns a prescription drug to a pharmacy that is permitted under chapter 465 and located in this state, provided that:

1. The consignor wholesale distributor notifies the department in writing of the contract to consign prescription drugs to a pharmacy along with the identity and location of each consignee pharmacy;

2. The pharmacy maintains its permit under chapter 465;

3. The consignor wholesale distributor, which has no legal authority to dispense prescription drugs, complies with all wholesale distribution requirements of ss. 499.0121 and 499.01212 with respect to the consigned drugs and maintains records documenting the transfer of title or other completion of the wholesale distribution of the consigned prescription drugs;

4. The distribution of the prescription drug is otherwise lawful under this chapter and other applicable law;

5. Open packages containing prescription drugs within a pharmacy are the responsibility of the pharmacy, regardless of how the drugs are titled; and
6. The pharmacy dispenses the consigned prescription drug in accordance with the limitations of its permit under chapter 465 or returns the consigned prescription drug to the consignor wholesale distributor. In addition, a person who holds title to prescription drugs may transfer the drugs to a person permitted or licensed to handle the reverse distribution or destruction of drugs. Any other distribution by and means of the consigned prescription drug by any person, not limited to the consignor wholesale distributor or consignee pharmacy, to any other person is prohibited.

(b) A wholesale distributor’s permit is not required for the one-time transfer of title of a pharmacy’s lawfully acquired prescription drug inventory by a pharmacy with a valid permit issued under chapter 465 to a consignor prescription drug wholesale distributor, permitted under this chapter, in accordance with a written consignment agreement between the pharmacy and that wholesale distributor if the permitted pharmacy and the permitted prescription drug wholesale distributor comply with all of the provisions of paragraph (a) and the prescription drugs continue to be within the permitted pharmacy’s inventory for dispensing in accordance with the limitations of the pharmacy permit under chapter 465. A consignor drug wholesale distributor may not use the pharmacy as a wholesale distributor through which it distributes the prescription drugs to other pharmacies. Nothing in this section is intended to prevent a wholesale distributor from obtaining this inventory in the event of nonpayment by the pharmacy.

(c) A separate establishment permit is not required when a permitted prescription drug wholesale distributor operates temporary transit storage facilities for the sole purpose of storage, for up to 16 hours, of a delivery of prescription drugs when the wholesale distributor was temporarily unable to complete the delivery to the recipient.

(d) The department shall require information from each wholesale distributor as part of the permit and renewal of such permit, as required under this section.

(13)(14) Personnel employed in wholesale distribution must have appropriate education and experience to enable them to perform their duties in compliance with state permitting requirements.

(14)(15) The name of a permittee or establishment on a prescription drug wholesale distributor permit or an out-of-state prescription drug wholesale distributor permit may not include any indicia of attainment of any educational degree, any indicia that the permittee or establishment possesses a professional license, or any name or abbreviation that the department determines is likely to cause confusion or mistake or that the department determines is deceptive, including that of any other entity authorized to purchase prescription drugs.

(15)(16)(a) Each establishment that is issued an initial or renewal permit as a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor must designate in writing to the
department at least one natural person to serve as the designated representative of the wholesale distributor. Such person must have an active certification as a designated representative from the department.

(b) To be certified as a designated representative, a natural person must:

1. Submit an application on a form furnished by the department and pay the appropriate fees.
2. Be at least 18 years of age.
3. Have at least 2 years of verifiable full-time:
   a. Work experience in a pharmacy licensed in this state or another state, where the person’s responsibilities included, but were not limited to, recordkeeping for prescription drugs;
   b. Managerial experience with a prescription drug wholesale distributor licensed in this state or in another state; or
   c. Managerial experience with the United States Armed Forces, where the person’s responsibilities included, but were not limited to, recordkeeping, warehousing, distributing, or other logistics services pertaining to prescription drugs.
4. Receive a passing score of at least 75 percent on an examination given by the department regarding federal laws governing distribution of prescription drugs and this part and the rules adopted by the department governing the wholesale distribution of prescription drugs. This requirement shall be effective 1 year after the results of the initial examination are mailed to the persons that took the examination. The department shall offer such examinations at least four times each calendar year.
5. Provide the department with a personal information statement and fingerprints pursuant to subsection (9).

(c) The department may deny an application for certification as a designated representative or may suspend or revoke a certification of a designated representative pursuant to s. 499.067.

(d) A designated representative:

1. Must be actively involved in and aware of the actual daily operation of the wholesale distributor.
2. Must be employed full time in a managerial position by the wholesale distributor.
3. Must be physically present at the establishment during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation, or other authorized absence.
4. May serve as a designated representative for only one wholesale distributor at any one time.

(e) A wholesale distributor must notify the department when a designated representative leaves the employ of the wholesale distributor. Such notice must be provided to the department within 10 business days after the last day of designated representative’s employment with the wholesale distributor.

(f) A wholesale distributor may not operate under a prescription drug wholesale distributor permit or an out-of-state prescription drug wholesale distributor permit for more than 10 business days after the designated representative leaves the employ of the wholesale distributor, unless the wholesale distributor employs another designated representative and notifies the department within 10 business days of the identity of the new designated representative.

Section 8. Section 499.01201, Florida Statutes, is amended to read:

499.01201 Agency for Health Care Administration review and use of statute and rule violation or compliance data.—Notwithstanding any other provision of law to the contrary, the Agency for Health Care Administration may not:

1. Review or use any violation or alleged violation of s. 499.0121(6) or s. 499.01212, or any rules adopted under those sections, as a ground for denying or withholding any payment of a Medicaid reimbursement to a pharmacy licensed under chapter 465; or

2. Review or use compliance with s. 499.0121(6) or s. 499.01212, or any rules adopted under those sections, as the subject of any audit of Medicaid-related records held by a pharmacy licensed under chapter 465.

Section 9. Paragraph (d) of subsection (4), subsection (6), and paragraph (b) of subsection (15) of section 499.0121, Florida Statutes, are amended to read:

499.0121 Storage and handling of prescription drugs; recordkeeping.—The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

4. EXAMINATION OF MATERIALS AND RECORDS.—

(d) Upon receipt, a wholesale distributor must review records required under this section for the acquisition of prescription drugs for accuracy and completeness, considering the total facts and circumstances surrounding the transactions and the wholesale distributors involved. This includes...
authenticating each transaction listed on a pedigree paper, as defined in s. 499.003(37).

(6) RECORDKEEPING.—The department shall adopt rules that require keeping such records of prescription drugs, including active pharmaceutical ingredients, as are necessary for the protection of the public health.

(a) The following persons must maintain business records that include the information specified in paragraph (b) Wholesale distributors must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records must provide a complete audit trail from receipt to sale or other disposition, be readily retrievable for inspection, and include, at a minimum, the following information:

1. Persons permitted or required to be permitted under chapter 499 to engage in the manufacture, repackaging, or distribution of active pharmaceutical ingredients or prescription drugs. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

2. Persons other than those set forth in subparagraph 1. that engage in the receipt of active pharmaceutical ingredients or prescription drugs. The name, principal address, and state license permit or registration number of the person authorized to purchase prescription drugs;

3. The name, strength, dosage form, and quantity of the drugs received and distributed or disposed of;

4. The dates of receipt and distribution or other disposition of the drugs; and

5. Any financial documentation supporting the transaction.

(b) Business records for persons specified in paragraph (a) must include:

1. The name and address of the seller, and the Florida permit number of the seller if such seller is not exempt from Florida permitting requirements, of the active pharmaceutical ingredient or prescription drug.

2. The address of the location the active pharmaceutical ingredient or prescription drug was shipped from.

3. The distribution date of the active pharmaceutical ingredient or prescription drug.

4. The name, strength, and quantity, and the National Drug Code if such code has been assigned, of the distributed active pharmaceutical ingredient or prescription drug.
5. The name and Florida permit number of the person that purchased the active pharmaceutical ingredient or prescription drug.

6. The financial data, including the unit type and unit price, for the distributions involving active pharmaceutical ingredients or prescription drugs.

7. The date and method of disposition of the active pharmaceutical ingredient or prescription drug. Inventories and records must be made available for inspection and photocopying by authorized federal, state, or local officials for a period of 2 years following disposition of the drugs or 3 years after the creation of the records, whichever period is longer.

(c) Each manufacturer or repackager of medical devices, over-the-counter drugs, or cosmetics must maintain business records that include:

1. The name and address of the seller or transferor of the product.

2. The address of the location the product was shipped from.

3. The date of the sale or distribution of the product.

4. The name and quantity of the product involved.

5. The name and address of the person who purchased the product. Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means must be readily available for authorized inspection during the retention period. Records that are kept at a central location outside of this state and that are not electronically retrievable must be made available for inspection within 2 working days after a request by an authorized official of a federal, state, or local law enforcement agency. Records that are maintained at a central location within this state must be maintained at an establishment that is permitted pursuant to this part and must be readily available.

(d) Persons permitted, or required to be permitted, under this chapter to engage in the manufacture, repackaging, or distribution of active pharmaceutical ingredients or prescription drugs; or the manufacture or repackaging of medical devices, over-the-counter drugs, and cosmetics; must establish, maintain, or have the capability to create a current inventory of the active pharmaceutical ingredients, prescription drugs, over-the-counter drugs, cosmetics, and devices at an establishment where activities specified in this paragraph are undertaken and must be able to produce such inventory for inspection by the department within 2 business days. Each manufacturer or repackager of medical devices, over-the-counter drugs, cosmetics must maintain records that include the name and principal address of the seller or transferor of the product, the address of the location from which the product was shipped, the date of the transaction, the name and quantity of the product involved, and the name and principal address of the person who purchased the product.

CODING: Words stricken are deletions; words underlined are additions.
(e) Business records required to be kept pursuant to this section, and that are kept at the inspection site or can be immediately retrieved by computer or other electronic means, must be readily available for authorized inspection during the retention period. Records kept at a central location outside of this state which are not electronically retrievable must be made available for inspection within 2 working days after a request by an authorized official of a federal, state, or local law enforcement agency. Records maintained at a central location within this state must be maintained at an establishment that is permitted pursuant to this part and such records must be readily available for inspection. When pedigree papers are required by this part, a wholesale distributor must maintain the pedigree papers separate and distinct from other records required under this part.

(f) Records required to be kept pursuant to this subsection must be maintained as specified for a period of not less than 6 years from the date of disposition of the active pharmaceutical ingredients, prescription drugs, over-the-counter drugs, medical devices, or cosmetics.

(g) To the extent that prescription drugs are also products as defined in the federal act, as amended, and the information required by the business records requirements of this section are also included in the tracking and tracing requirements of the federal act, as amended, and departmental rules, the manufacturer, wholesale distributor, repackager, or dispenser must follow both the requirements of the federal act, as amended, and departmental rules.

(15) DUE DILIGENCE OF PURCHASERS.—

(b) A wholesale distributor must take reasonable measures to identify its customers, understand the normal and expected transactions conducted by those customers, and identify those transactions that are suspicious in nature. A wholesale distributor must establish internal policies and procedures for identifying suspicious orders and preventing suspicious transactions. A wholesale distributor must assess orders for more than 7,500 unit doses of any one controlled substance in any one month to determine whether the purchase is reasonable. In making such assessments, a wholesale distributor may consider the purchasing entity’s clinical business needs, location, and population served, in addition to other factors established in the distributor’s policies and procedures. A wholesale distributor must report to the department any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the law. The wholesale distributor shall maintain records that document the report submitted to the department in compliance with this paragraph.
499.015 Registration of drugs, devices, and cosmetics; issuance of certificates of free sale.—

(4) Unless a registration is renewed, it expires 2 years after the last day of the month in which it was issued. Any product registration issued or renewed on or after July 1, 2016, shall expire on the same date as the manufacturer or repackager permit of the person seeking to register the product. If the first product registration issued to a person on or after July 1, 2016, expires less than 366 days after issuance, the fee for product registration shall be $15. If the first product registration issued to a person on or after July 1, 2016, expires more than 365 days after issuance, the fee for product registration shall be $30. The department may issue a stop-sale notice or order against a person that is subject to the requirements of this section and that fails to comply with this section within 31 days after the date the registration expires. The notice or order shall prohibit such person from selling or causing to be sold any drugs, devices, or cosmetics covered by this part until he or she complies with the requirements of this section.

Section 11. Subsection (1) of section 499.03, Florida Statutes, is amended to read:

499.03 Possession of certain drugs without prescriptions unlawful; exemptions and exceptions.—

(1) A person may not possess, or possess with intent to sell, dispense, or deliver, any habit-forming, toxic, harmful, or new drug subject to s. 499.003(32) 499.003(33), or prescription drug as defined in s. 499.003(40) 499.003(43), unless the possession of the drug has been obtained by a valid prescription of a practitioner licensed by law to prescribe the drug. However, this section does not apply to the delivery of such drugs to persons included in any of the classes named in this subsection, or to the agents or employees of such persons, for use in the usual course of their businesses or practices or in the performance of their official duties, as the case may be; nor does this section apply to the possession of such drugs by those persons or their agents or employees for such use:

(a) A licensed pharmacist or any person under the licensed pharmacist’s supervision while acting within the scope of the licensed pharmacist’s practice;

(b) A licensed practitioner authorized by law to prescribe prescription drugs or any person under the licensed practitioner’s supervision while acting within the scope of the licensed practitioner’s practice;

(c) A qualified person who uses prescription drugs for lawful research, teaching, or testing, and not for resale;

(d) A licensed hospital or other institution that procures such drugs for lawful administration or dispensing by practitioners;

(e) An officer or employee of a federal, state, or local government; or

CODING: Words stricken are deletions; words underlined are additions.
(f) A person that holds a valid permit issued by the department pursuant to this part which authorizes that person to possess prescription drugs.

Section 12. Paragraphs (i) through (p) of subsection (1) of section 499.05, Florida Statutes, are amended to read:

499.05 Rules.—

(1) The department shall adopt rules to implement and enforce this chapter with respect to:

(i) Additional conditions that qualify as an emergency medical reason under s. 499.003(48)(b)2, 499.003(53)(b)2, or s. 499.82.

(j) Procedures and forms relating to the pedigree paper requirement of s. 499.01212.

(k) The protection of the public health, safety, and welfare regarding good manufacturing practices that manufacturers and repackagers must follow to ensure the safety of the products.

(l) Information required from each retail establishment pursuant to s. 499.012(3) or s. 499.83(2)(c), including requirements for prescriptions or orders.

(m) The recordkeeping, storage, and handling with respect to each of the distributions of prescription drugs specified in s. 499.003(48)(a)-(v) 499.003(53)(a)-(d) or s. 499.82(14).

(n) Alternatives to compliance with s. 499.01212 for a prescription drug in the inventory of a permitted prescription drug wholesale distributor as of June 30, 2006, and the return of a prescription drug purchased prior to July 1, 2006. The department may specify time limits for such alternatives.

(o) Wholesale distributor reporting requirements of s. 499.0121(14).

(p) Wholesale distributor credentialing and distribution requirements of s. 499.0121(15).

Section 13. Subsection (7) of section 499.051, Florida Statutes, is amended to read:

499.051 Inspections and investigations.—

(7) The complaint and all information obtained pursuant to the investigation by the department are confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution until the investigation and the enforcement action are completed. However, trade secret information contained therein as defined by s. 812.081(1)(c) shall remain confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution, as long as the information is retained by the department. This subsection does not prohibit the department from using
such information for regulatory or enforcement proceedings under this chapter or from providing such information to any law enforcement agency or any other regulatory agency. However, the receiving agency shall keep such records confidential and exempt as provided in this subsection. In addition, this subsection is not intended to prevent compliance with the provisions of s. 499.01212, and the pedigree papers required in that section shall not be deemed a trade secret.

Section 14. Subsection (14) of section 499.82, Florida Statutes, is amended to read:

499.82 Definitions.—As used in this part, the term:

(14) “Wholesale distribution” means the distribution of medical gas to a person other than a consumer or patient. Wholesale distribution of medical gases does not include:

(a) The sale, purchase, or trade of a medical gas; an offer to sell, purchase, or trade a medical gas; or the dispensing of a medical gas pursuant to a prescription;

(b) Activities exempt from the definition of wholesale distribution in s. 499.003; or

(c) The sale, purchase, or trade of a medical gas or an offer to sell, purchase, or trade a medical gas for emergency medical reasons; or

(d) Other transactions excluded from the definition of wholesale distribution under the federal act or regulations implemented under the federal act related to medical gas.

Section 15. Subsection (6) of section 499.83, Florida Statutes, is created to read:

499.83 Permits.—

(6) A hospice licensed by the Agency for Health Care Administration pursuant to part IV of chapter 400 is not required to obtain medical oxygen retail establishment permit to purchase on behalf of and sell medical oxygen to its hospice patients, if the hospice contracts for the purchase and delivery of medical oxygen from an establishment permitted pursuant to this part. Sale and delivery to patients by hospices pursuant to this subsection must be based upon a prescription or an order from a practitioner authorized by law to prescribe medical oxygen. For sales to hospices pursuant to this subsection, the medical gas wholesale distributor or the medical gas manufacturer selling medical oxygen to a hospice shall reflect on its invoice the hospice license number provided by the Agency for Health Care Administration and shall maintain such record pursuant to s. 499.89.

Both the hospice and the medical oxygen retailer delivering medical oxygen to the patient must maintain a copy of a valid order or prescription for medical oxygen.

CODING: Words stricken are deletions; words underlined are additions.
medical oxygen in accordance with s. 499.89 and department rule, which copy must be readily available for inspection.

Section 16. Subsection (4) of section 499.89, Florida Statutes, is amended to read:

499.89 Recordkeeping.—

(4) A pedigree paper is not required for distributing or dispensing medical gas.

Section 17. Section 499.01212, Florida Statutes, is repealed.

Section 18. Paragraph (a) of subsection (1) of section 409.9201, Florida Statutes, is amended to read:

409.9201 Medicaid fraud.—

(1) As used in this section, the term:

(a) “Prescription drug” means any drug, including, but not limited to, finished dosage forms or active ingredients that are subject to, defined in, or described in s. 503(b) of the Federal Food, Drug, and Cosmetic Act or in s. 465.003(8), s. 499.003(47), s. 499.007(13), or s. 499.82(10).

The value of individual items of the legend drugs or goods or services involved in distinct transactions committed during a single scheme or course of conduct, whether involving a single person or several persons, may be aggregated when determining the punishment for the offense.

Section 19. Paragraph (b) of subsection (1) of section 499.067, Florida Statutes, is amended to read:

499.067 Denial, suspension, or revocation of permit, certification, or registration.—

(1)

(b) The department may deny an application for a permit or certification, or suspend or revoke a permit or certification, if the department finds that:

1. The applicant is not of good moral character or that it would be a danger or not in the best interest of the public health, safety, and welfare if the applicant were issued a permit or certification.

2. The applicant has not met the requirements for the permit or certification.

3. The applicant is not eligible for a permit or certification for any of the reasons enumerated in s. 499.012.

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4. The applicant, permittee, or person certified under s. 499.012(15) s. 499.012(16) demonstrates any of the conditions enumerated in s. 499.012.

5. The applicant, permittee, or person certified under s. 499.012(15) s. 499.012(16) has committed any violation of this chapter.

Section 20. Subsection (1) of section 794.075, Florida Statutes, is amended to read:

794.075 Sexual predators; erectile dysfunction drugs.—

(1) A person may not possess a prescription drug, as defined in s. 499.003(40) s. 499.003(43), for the purpose of treating erectile dysfunction if the person is designated as a sexual predator under s. 775.21.

Section 21. Paragraphs (d), (f), (i), and (j) of subsection (3) of section 921.0022, Florida Statutes, are amended to read:

921.0022 Criminal Punishment Code; offense severity ranking chart.—

(3) OFFENSE SEVERITY RANKING CHART

(d) LEVEL 4

<table>
<thead>
<tr>
<th>Florida Statute</th>
<th>Felony Degree</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>316.1935(3)(a)</td>
<td>2nd</td>
<td>Driving at high speed or with wanton disregard for safety while fleeing or attempting to elude law enforcement officer who is in a patrol vehicle with siren and lights activated.</td>
</tr>
<tr>
<td>499.0051(1)</td>
<td>3rd</td>
<td>Failure to maintain or deliver transaction history, transaction information, or transaction statements pedigree papers.</td>
</tr>
<tr>
<td>499.0051(2)</td>
<td>3rd</td>
<td>Failure to authenticate pedigree papers.</td>
</tr>
<tr>
<td>499.0051(5)</td>
<td>2nd</td>
<td>Knowing sale or delivery, or possession with intent to sell, contraband prescription drugs.</td>
</tr>
<tr>
<td>517.07(1)</td>
<td>3rd</td>
<td>Failure to register securities.</td>
</tr>
<tr>
<td>517.12(1)</td>
<td>3rd</td>
<td>Failure of dealer, associated person, or issuer of securities to register.</td>
</tr>
<tr>
<td>784.07(2)(b)</td>
<td>3rd</td>
<td>Battery of law enforcement officer, firefighter, etc.</td>
</tr>
<tr>
<td>784.074(1)(c)</td>
<td>3rd</td>
<td>Battery of sexually violent predators facility staff.</td>
</tr>
<tr>
<td>784.075</td>
<td>3rd</td>
<td>Battery on detention or commitment facility staff.</td>
</tr>
<tr>
<td>784.078</td>
<td>3rd</td>
<td>Battery of facility employee by throwing, tossing, or expelling certain fluids or materials.</td>
</tr>
</tbody>
</table>

CODING: Words stricken are deletions; words underlined are additions.
784.08(2)(c) 3rd  Battery on a person 65 years of age or older.
784.081(3) 3rd  Battery on specified official or employee.
784.082(3) 3rd  Battery by detained person on visitor or other detainee.
784.083(3) 3rd  Battery on code inspector.
784.085 3rd  Battery of child by throwing, tossing, projecting, or expelling certain fluids or materials.
787.03(1) 3rd  Interference with custody; wrongly takes minor from appointed guardian.
787.04(2) 3rd  Take, entice, or remove child beyond state limits with criminal intent pending custody proceedings.
787.04(3) 3rd  Carrying child beyond state lines with criminal intent to avoid producing child at custody hearing or delivering to designated person.
787.07 3rd  Human smuggling.
790.115(1) 3rd  Exhibiting firearm or weapon within 1,000 feet of a school.
790.115(2)(b) 3rd  Possessing electric weapon or device, destructive device, or other weapon on school property.
790.115(2)(c) 3rd  Possessing firearm on school property.
800.04(7)(c) 3rd  Lewd or lascivious exhibition; offender less than 18 years.
810.02(4)(a) 3rd  Burglary, or attempted burglary, of an unoccupied structure; unarmed; no assault or battery.
810.02(4)(b) 3rd  Burglary, or attempted burglary, of an unoccupied conveyance; unarmed; no assault or battery.
810.06 3rd  Burglary; possession of tools.
810.08(2)(c) 3rd  Trespass on property, armed with firearm or dangerous weapon.
812.014(2)(c)3. 3rd  Grand theft, 3rd degree $10,000 or more but less than $20,000.
812.014 (2)(c)4.-10. 3rd  Grand theft, 3rd degree, a will, firearm, motor vehicle, livestock, etc.
812.0195(2) 3rd  Dealing in stolen property by use of the Internet; property stolen $300 or more.
817.563(1) 3rd  Sell or deliver substance other than controlled substance agreed upon, excluding s. 893.03(5) drugs.
817.568(2)(a) 3rd  Fraudulent use of personal identification information.
817.625(2)(a) 3rd  Fraudulent use of scanning device or reencoder.
828.125(1) 2nd Kill, maim, or cause great bodily harm or permanent breeding disability to any registered horse or cattle.

837.02(1) 3rd Perjury in official proceedings.

837.021(1) 3rd Make contradictory statements in official proceedings.

838.022 3rd Official misconduct.

839.13(2)(a) 3rd Falsifying records of an individual in the care and custody of a state agency.

839.13(2)(c) 3rd Falsifying records of the Department of Children and Families.

843.021 3rd Possession of a concealed handcuff key by a person in custody.

843.025 3rd Deprive law enforcement, correctional, or correctional probation officer of means of protection or communication.

843.15(1)(a) 3rd Failure to appear while on bail for felony (bond estreature or bond jumping).

847.0135(5)(c) 3rd Lewd or lascivious exhibition using computer; offender less than 18 years.

874.05(1)(a) 3rd Encouraging or recruiting another to join a criminal gang.

893.13(2)(a) 2nd Purchase of cocaine (or other s.

914.14(2) 3rd Witnesses accepting bribes.

914.22(1) 3rd Force, threaten, etc., witness, victim, or informant.

914.23(2) 3rd Retaliation against a witness, victim, or informant, no bodily injury.

918.12 3rd Tampering with jurors.

934.215 3rd Use of two-way communications device to facilitate commission of a crime.

(f) LEVEL 6

<table>
<thead>
<tr>
<th>Florida Statute</th>
<th>Felony Degree</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>316.027(2)(b)</td>
<td>2nd</td>
<td>Leaving the scene of a crash involving serious bodily injury.</td>
</tr>
<tr>
<td>316.193(2)(b)</td>
<td>3rd</td>
<td>Felony DUI, 4th or subsequent conviction.</td>
</tr>
<tr>
<td>400.9935(4)(c)</td>
<td>2nd</td>
<td>Operating a clinic, or offering services requiring licensure, without a license.</td>
</tr>
<tr>
<td>499.0051(2)</td>
<td>2nd</td>
<td>Knowing forgery of transaction history, transaction information, or transaction statement pedigree papers.</td>
</tr>
<tr>
<td>499.0051(3)</td>
<td>2nd</td>
<td>Knowing purchase or receipt of prescription drug from unauthorized person.</td>
</tr>
<tr>
<td>499.0051(4)</td>
<td>2nd</td>
<td>Knowing sale or transfer of prescription drug to unauthorized person.</td>
</tr>
<tr>
<td>499.0051(5)</td>
<td>2nd</td>
<td>Knowing forgery of transaction history, transaction information, or transaction statement pedigree papers.</td>
</tr>
</tbody>
</table>

CODING: Words stricken are deletions; words underlined are additions.
775.0875(1) 3rd Taking firearm from law enforcement officer.
784.021(1)(a) 3rd Aggravated assault; deadly weapon without intent to kill.
784.021(1)(b) 3rd Aggravated assault; intent to commit felony.
784.041 3rd Felony battery; domestic battery by strangulation.
784.048(3) 3rd Aggravated stalking; credible threat.
784.048(5) 3rd Aggravated stalking of person under 16.
784.07(2)(c) 2nd Aggravated assault on law enforcement officer.
784.074(1)(b) 2nd Aggravated assault on sexually violent predators facility staff.
784.08(2)(b) 2nd Aggravated assault on a person 65 years of age or older.
784.081(2) 2nd Aggravated assault on specified official or employee.
784.082(2) 2nd Aggravated assault by detained person on visitor or other detainee.
784.083(2) 2nd Aggravated assault on code inspector.
787.02(2) 3rd False imprisonment; restraining with purpose other than those in s. 787.01.
790.115(2)(d) 2nd Discharging firearm or weapon on school property.
790.161(2) 2nd Make, possess, or throw destructive device with intent to do bodily harm or damage property.
790.164(1) 2nd False report of deadly explosive, weapon of mass destruction, or act of arson or violence to state property.
790.19 2nd Shooting or throwing deadly missiles into dwellings, vessels, or vehicles.
794.011(8)(a) 3rd Solicitation of minor to participate in sexual activity by custodial adult.
794.05(1) 2nd Unlawful sexual activity with specified minor.
800.04(5)(d) 3rd Lewd or lascivious molestation; victim 12 years of age or older but less than 16 years of age; offender less than 18 years.
800.04(6)(b) 2nd Lewd or lascivious conduct; offender 18 years of age or older.
806.031(2) 2nd Arson resulting in great bodily harm to firefighter or any other person.
810.02(3)(c) 2nd Burglary of occupied structure; unarmed; no assault or battery.
810.145(8)(b) 2nd Video voyeurism; certain minor victims; 2nd or subsequent offense.

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812.014(2)(b)1. 2nd Property stolen $20,000 or more, but less than $100,000, grand theft in 2nd degree.

812.014(6) 2nd Theft; property stolen $3,000 or more; coordination of others.

812.015(9)(a) 2nd Retail theft; property stolen $300 or more; second or subsequent conviction.

812.015(9)(b) 2nd Retail theft; property stolen $3,000 or more; coordination of others.

812.13(2)(c) 2nd Robbery, no firearm or other weapon (strong-arm robbery).

817.4821(5) 2nd Possess cloning paraphernalia with intent to create cloned cellular telephones.

825.102(1) 3rd Abuse of an elderly person or disabled adult.

825.102(3)(c) 3rd Neglect of an elderly person or disabled adult.

825.1025(3) 3rd Lewd or lascivious molestation of an elderly person or disabled adult.

825.103(3)(c) 3rd Exploiting an elderly person or disabled adult and property is valued at less than $10,000.

827.03(2)(c) 3rd Abuse of a child.

827.03(2)(d) 3rd Neglect of a child.

827.071(2) & (3) 2nd Use or induce a child in a sexual performance, or promote or direct such performance.

836.05 2nd Threats; extortion.

836.10 2nd Written threats to kill or do bodily injury.

843.12 3rd Aids or assists person to escape.

847.011 3rd Distributing, offering to distribute, or possessing with intent to distribute obscene materials depicting minors.

847.012 3rd Knowingly using a minor in the production of materials harmful to minors.

847.0135(2) 3rd Facilitates sexual conduct of or with a minor or the visual depiction of such conduct.

914.23 2nd Retaliation against a witness, victim, or informant, with bodily injury.

944.35(3)(a)2. 3rd Committing malicious battery upon or inflicting cruel or inhuman treatment on an inmate or offender on community supervision, resulting in great bodily harm.

944.40 2nd Escapes.

944.46 3rd Harboring, concealing, aiding escaped prisoners.

CODING: Words stricken are deletions; words underlined are additions.
944.47(1)(a)5. 2nd Introduction of contraband (firearm, weapon, or explosive) into correctional facility.

951.22(1) 3rd Intoxicating drug, firearm, or weapon introduced into county facility.

(i) LEVEL 9

<table>
<thead>
<tr>
<th>Florida Statute</th>
<th>Felony Degree</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>316.193(3)(c)3.b.</td>
<td>1st</td>
<td>DUI manslaughter; failing to render aid or give information.</td>
</tr>
<tr>
<td>327.35(3)(c)3.b.</td>
<td>1st</td>
<td>BUI manslaughter; failing to render aid or give information.</td>
</tr>
<tr>
<td>409.920(2)(b)1.c.</td>
<td>1st</td>
<td>Medicaid provider fraud; $50,000 or more.</td>
</tr>
<tr>
<td>499.0051(8)</td>
<td>1st</td>
<td>Knowing sale or purchase of contraband prescription drugs resulting in great bodily harm.</td>
</tr>
<tr>
<td>499.0051(9)</td>
<td>1st</td>
<td>-</td>
</tr>
<tr>
<td>560.123(8)(b)3.</td>
<td>1st</td>
<td>Failure to report currency or payment instruments totaling or exceeding $100,000 by money transmitter.</td>
</tr>
<tr>
<td>560.125(5)(c)</td>
<td>1st</td>
<td>Money transmitter business by unauthorized person, currency, or payment instruments totaling or exceeding $100,000.</td>
</tr>
<tr>
<td>655.50(10)(b)3.</td>
<td>1st</td>
<td>Failure to report financial transactions totaling or exceeding $100,000 by financial institution.</td>
</tr>
<tr>
<td>775.0844</td>
<td>1st</td>
<td>Aggravated white collar crime.</td>
</tr>
<tr>
<td>782.04(1)</td>
<td>1st</td>
<td>Attempt, conspire, or solicit to commit premeditated murder.</td>
</tr>
<tr>
<td>782.04(3)</td>
<td>1st,PBL</td>
<td>Accomplice to murder in connection with arson, sexual battery, robbery, burglary, aggravated fleeing or eluding with serious bodily injury or death, and other specified felonies.</td>
</tr>
<tr>
<td>782.051(1)</td>
<td>1st</td>
<td>Attempted felony murder while perpetrating or attempting to perpetrate a felony enumerated in s. 782.04(3).</td>
</tr>
<tr>
<td>782.07(2)</td>
<td>1st</td>
<td>Aggravated manslaughter of an elderly person or disabled adult.</td>
</tr>
<tr>
<td>787.01(1)(a)1.</td>
<td>1st,PBL</td>
<td>Kidnapping; hold for ransom or reward or as a shield or hostage.</td>
</tr>
<tr>
<td>787.01(1)(a)2.</td>
<td>1st,PBL</td>
<td>Kidnapping with intent to commit or facilitate commission of any felony.</td>
</tr>
<tr>
<td>787.01(1)(a)4.</td>
<td>1st,PBL</td>
<td>Kidnapping with intent to interfere with performance of any governmental or political function.</td>
</tr>
</tbody>
</table>

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787.02(3)(a) 1st,PBL False imprisonment; child under age 13; perpetrator also commits aggravated child abuse, sexual battery, or lewd or lascivious battery, molestation, conduct, or exhibition.

787.06(3)(c)1. 1st Human trafficking for labor and services of an unauthorized alien child.

787.06(3)(d) 1st Human trafficking using coercion for commercial sexual activity of an unauthorized adult alien.

787.06(3)(f)1. 1st,PBL Human trafficking for commercial sexual activity by the transfer or transport of any child from outside Florida to within the state.

790.161 1st Attempted capital destructive device offense.

790.166(2) 1st,PBL Possessing, selling, using, or attempting to use a weapon of mass destruction.

794.011(2) 1st Attempted sexual battery; victim less than 12 years of age.

794.011(2) Life Sexual battery; offender younger than 18 years and commits sexual battery on a person less than 12 years.

794.011(4)(a) 1st,PBL Sexual battery, certain circumstances; victim 12 years of age or older but younger than 18 years; offender 18 years or older.

794.011(4)(b) 1st Sexual battery, certain circumstances; victim and offender 18 years of age or older.

794.011(4)(c) 1st Sexual battery, certain circumstances; victim 12 years of age or older; offender younger than 18 years.

794.011(4)(d) 1st,PBL Sexual battery, certain circumstances; victim 12 years of age or older; prior conviction for specified sex offenses.

794.011(8)(b) 1st,PBL Sexual battery; engage in sexual conduct with minor 12 to 18 years by person in familial or custodial authority.

794.08(2) 1st Female genital mutilation; victim younger than 18 years of age.

800.04(5)(b) Life Lewd or lascivious molestation; victim less than 12 years; offender 18 years or older.

812.13(2)(a) 1st,PBL Robbery with firearm or other deadly weapon.

812.133(2)(a) 1st,PBL Carjacking; firearm or other deadly weapon.

812.135(2)(b) 1st Home-invasion robbery with weapon.
817.535(3)(b) 1st  Filing false lien or other unauthorized document; second or subsequent offense; property owner is a public officer or employee.

817.535(4)(a)2. 1st  Filing false claim or other unauthorized document; defendant is incarcerated or under supervision.

817.535(5)(b) 1st  Filing false lien or other unauthorized document; second or subsequent offense; owner of the property incurs financial loss as a result of the false instrument.

817.568(7) 2nd, PBL  Fraudulent use of personal identification information of an individual under the age of 18 by his or her parent, legal guardian, or person exercising custodial authority.

827.03(2)(a) 1st  Aggravated child abuse.

847.0145(1) 1st  Selling, or otherwise transferring custody or control, of a minor.

847.0145(2) 1st  Purchasing, or otherwise obtaining custody or control, of a minor.

859.01 1st  Poisoning or introducing bacteria, radioactive materials, viruses, or chemical compounds into food, drink, medicine, or water with intent to kill or injure another person.

893.135 1st  Attempted capital trafficking offense.

893.135(1)(a)3. 1st  Trafficking in cannabis, more than 10,000 lbs.

893.135 1st  Trafficking in cocaine, more than 400 grams, less than 150 kilograms.

893.135 1st  Trafficking in illegal drugs, more than 28 grams, less than 30 kilograms.

893.135 1st  Trafficking in hydrocodone, 200 grams or more, less than 30 kilograms.

893.135 1st  Trafficking in oxycodone, 100 grams or more, less than 30 kilograms.

893.135 1st  Trafficking in phencyclidine, more than 400 grams.

893.135 1st  Trafficking in methaqualone, more than 25 kilograms.

893.135 1st  Trafficking in amphetamine, more than 200 grams.

893.135 1st  Trafficking in gamma-hydroxybutyric acid (GHB), 10 kilograms or more.

893.135 1st  Trafficking in 1,4-Butanediol, 10 kilograms or more.

893.135 1st  Trafficking in Phenethylamines, 400 grams or more.

CODING: Words stricken are deletions; words underlined are additions.
896.101(5)(c) 1st Money laundering, financial instruments totaling or exceeding $100,000.
896.104(4)(a)3. 1st Structuring transactions to evade reporting or registration requirements, financial transactions totaling or exceeding $100,000.

(j) LEVEL 10

<table>
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<tr>
<th>Florida Statute</th>
<th>Felony Degree</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>499.0051(9)</td>
<td>1st</td>
<td>Knowing sale or purchase of contraband prescription drugs resulting in death.</td>
</tr>
<tr>
<td>499.0051(10)</td>
<td>1st,PBL</td>
<td>Unlawful killing of human; act is homicide, unpremeditated.</td>
</tr>
<tr>
<td>782.04(2)</td>
<td>1st,PBL</td>
<td>Aggravated manslaughter of a child.</td>
</tr>
<tr>
<td>782.07(3)</td>
<td>1st</td>
<td>Kidnapping; inflict bodily harm upon or terrorize victim.</td>
</tr>
<tr>
<td>787.01(1)(a)3.</td>
<td>1st,PBL</td>
<td>Kidnapping; child under age 13, perpetrator also commits aggravated child abuse, sexual battery, or lewd or lascivious battery, molestation, conduct, or exhibition.</td>
</tr>
<tr>
<td>787.06(3)(g)</td>
<td>Life</td>
<td>Human trafficking for commercial sexual activity of a child under the age of 18 or mentally defective or incapacitated person.</td>
</tr>
<tr>
<td>787.06(4)(a)</td>
<td>Life</td>
<td>Selling or buying of minors into human trafficking.</td>
</tr>
<tr>
<td>794.011(3)</td>
<td>Life</td>
<td>Sexual battery; victim 12 years or older, offender uses or threatens to use deadly weapon or physical force to cause serious injury.</td>
</tr>
<tr>
<td>812.135(2)(a)</td>
<td>1st,PBL</td>
<td>Home-invasion robbery with firearm or other deadly weapon.</td>
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<tr>
<td>876.32</td>
<td>1st</td>
<td>Treason against the state.</td>
</tr>
</tbody>
</table>

Section 22. Section 893.30, Florida Statutes, is created to read:

893.30 Controlled substance safety education and awareness.—

(1) This section may be cited as the “Victoria Siegel Controlled Substance Safety Education and Awareness Act.”

(2) The department shall develop a written pamphlet relating to controlled substances which includes educational information about the following:

(a) Precautions regarding the use of pain management prescriptions.
(b) The potential for misuse and abuse of controlled substances by adults and children.

(c) The risk of controlled substance dependency and addiction.

(d) The proper storage and disposal of controlled substances.

(e) Controlled substance addiction support and treatment resources.

(f) Telephone helplines and website links that provide counseling and emergency assistance for individuals dealing with substance abuse.

(3) The department shall encourage health care providers, including, but not limited to, hospitals, county health departments, physicians, and nurses, to disseminate and display information about controlled substance safety, including, but not limited to, the pamphlet created pursuant to subsection (2).

(4) The department shall encourage consumers to discuss the risks of controlled substance use with their health care providers.

(5) The State Surgeon General shall make publicly available, by posting on the department’s website, the pamphlet created pursuant to subsection (2) and additional resources as appropriate.

(6) The department shall fund the promotion of controlled substance safety education and awareness under this section through grants from private or federal sources.

(7) The department is encouraged to collaborate with other agencies, organizations, and institutions to create a systematic approach to increasing public awareness regarding controlled substance safety.

Section 23. This act shall take effect July 1, 2016.

Approved by the Governor April 8, 2016.

Filed in Office Secretary of State April 8, 2016.
The following chart is a summary of the Division's current rulemaking efforts.

<table>
<thead>
<tr>
<th>Rule #</th>
<th>Title</th>
<th>Purpose</th>
<th>Status</th>
<th>Next Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>61N-1.001</td>
<td>General Regulations; Definitions</td>
<td>Define terms set forth in recent changes to Chapter 499, F.S. that become effective 7/1/16.</td>
<td>Notice of Development filed 5/5/16</td>
<td>Notice proposed rule language &amp; conduct public hearing.</td>
</tr>
<tr>
<td>61N-1.028</td>
<td>Product Tracking and Tracing – Definitions</td>
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<td></td>
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<tr>
<td>61N-1.029</td>
<td>Product Tracking and Tracing – Manufacturer Requirements</td>
<td>To adopt federal requirements pertaining to the tracking and tracing for entities that engage in the manufacture, repackaging, wholesale distribution, and dispensing of specific prescription drug products falling under Title II, Drug Supply Chain Security Act, of the federal Drug Quality and Security Act.</td>
<td>Rules filed for adoption with the Department of State.</td>
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</tr>
<tr>
<td>61N-1.030</td>
<td>Product Tracking and Tracing – Wholesale Distributor Requirements</td>
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<tr>
<td>61N-1.031</td>
<td>Product Tracking and Tracing – Dispenser Requirements</td>
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<tr>
<td>61N-1.032</td>
<td>Product Tracking and Tracing – Repackager Requirements</td>
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<tr>
<td>61N-2.001</td>
<td>Application for Complimentary Drug Distributor Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Change filed 4/22/16.</td>
<td></td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td>Purpose</td>
<td>Status</td>
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<tr>
<td>61N-2.007</td>
<td>Application for Limited Prescription Drug Veterinary Wholesale Distributor Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
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<tr>
<td>61N-2.008</td>
<td>Application for Medical Gas Manufacturer Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Change filed 4/22/16.</td>
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<tr>
<td>61N-2.009</td>
<td>Application for Medical Gas Wholesale Distributor Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Change filed 4/22/16.</td>
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<tr>
<td>61N-2.010</td>
<td>Application for Medical Oxygen Retail Establishment Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Change filed 4/22/16.</td>
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<tr>
<td>61N-2.011</td>
<td>Application for Nonresident Prescription Drug Manufacturer Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
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<tr>
<td>61N-2.0111</td>
<td>Application for Nonresident Prescription Drug Manufacturer – Virtual Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Development filed 5/5/16.</td>
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<tr>
<td>61N-2.012</td>
<td>Application for Out-of-State Prescription Drug Wholesale Distributor Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
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<tr>
<td>61N-2.013</td>
<td>Application for Over-the-counter Drug Manufacturer Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Change filed 4/22/16.</td>
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<tr>
<td>61N-2.014</td>
<td>Application for Prescription Drug Manufacturer Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Change filed 4/22/16.</td>
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<tr>
<td>61N-2.0141</td>
<td>Application for Prescription Drug Manufacturer – Virtual Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Development filed 5/5/16.</td>
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<tr>
<td>61N-2.015</td>
<td>Application for Prescription Drug Repackager Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
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<tr>
<td>61N-2.0151</td>
<td>Application for Nonresident Prescription Drug Repackager Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Development filed 5/5/16.</td>
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<tr>
<td>61N-2.016</td>
<td>Application for Prescription Drug Wholesale Distributor Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
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<tr>
<td>61N-2.017</td>
<td>Application for Prescription Drug Wholesale Distributor – Broker Only Permit</td>
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<td>Notice of Development filed 2/26/16.</td>
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<tr>
<td>61N-2.018</td>
<td>Application for Restricted Rx Drug Distributor – Blood Establishment Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
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<tr>
<td>61N-2.019</td>
<td>Application for Restricted Rx Drug Distributor – Charitable Organization Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
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<tr>
<td>61N-2.020</td>
<td>Application for Restricted Rx Drug Distributor –</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
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<tr>
<td>Destruction Permit</td>
<td>Application for Restricted Rx Drug Distributor – Government Programs Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
<td>File notice of rulemaking for rule and application.</td>
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<tr>
<td>61N-2.021</td>
<td>Application for Restricted Rx Drug Distributor – Health Care Entity Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
<td>File notice of rulemaking for rule and application.</td>
</tr>
<tr>
<td>61N-2.022</td>
<td>Application for Restricted Rx Drug Distributor – Institutional Research Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
<td>File notice of rulemaking for rule and application.</td>
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<tr>
<td>61N-2.023</td>
<td>Application for Restricted Rx Drug Distributor – Reverse Distributor</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
<td>File notice of rulemaking for rule and application.</td>
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<tr>
<td>61N-2.024</td>
<td>Application for Retail Pharmacy Drug Wholesale Distributor Permit</td>
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<td>Notice of Development filed 2/26/16.</td>
<td>File notice of rulemaking for rule and application.</td>
</tr>
<tr>
<td>61N-2.025</td>
<td>Application for Third Party Logistics Provider Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
<td>File notice of rulemaking for rule and application.</td>
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<tr>
<td>61N-2.026</td>
<td>Application for Veterinary Prescription Drug Retail Establishment</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
<td>File notice of rulemaking for rule and application.</td>
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<tr>
<td>61N-2.027</td>
<td>Application for Veterinary Prescription Drug Wholesale Distributor Permit</td>
<td>To adopt and incorporate the division’s permitting application forms into rule.</td>
<td>Notice of Development filed 2/26/16.</td>
<td>File notice of rulemaking for rule and application.</td>
</tr>
</tbody>
</table>
61N-1.028 Product Tracking and Tracing – Definitions.
The following definitions apply to the product tracking and tracing requirements set forth in Rules 61N-1.029, 61N-1.030, 61N-1.031 and 61N-1.032, F.A.C.

(1) “AFFILIATE” means a business entity that has a relationship with a second business entity if, directly or indirectly:
   (a) One business entity controls, or has the power to control, the other business entity; or
   (b) A third party controls, or has the power to control, both of the business entities.

(2) “AUTHORIZED” means:
   (a) A manufacturer or repackager, registered as a drug establishment with the FDA;
   (b) A wholesale distributor, having a valid license under Florida law or federal law, and complying with the licensure reporting requirements under 21 U.S.C. § 353(e), (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06713;
   (c) A third-party logistics provider, having a valid license under Florida law or federal law, and complying with the licensure reporting requirements under 21 U.S.C. § 360eee-3(b) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06714; and,
   (d) A dispenser, having a valid license under Florida law.

(3) “DISPENSER” means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor. Dispenser does not include a person who dispenses only products to be used in animals when the product is dispensed on the lawful written or oral order of a licensed veterinarian within the context of a veterinarian-client-patient relationship.

(4) “DISPOSITION” means, with respect to a product within the possession or control of an entity, the removal of such product from the pharmaceutical distribution supply chain, which may include disposal or return of the product for disposal or other handling or actions, such as retaining a sample of the product for further additional physical examination or laboratory analysis of the product by a manufacturer or regulatory or law enforcement agency.

(5) “DISTRIBUTE” or “DISTRIBUTION” means to sell, purchase, trade, deliver, handle, store, or receive a product. The term does not mean to administer or dispense and does not include the billing and invoicing activities that commonly follow a wholesale distribution transaction.

(6) “EXCLUSIVE DISTRIBUTOR” means the wholesale distributor that directly purchased the product from the manufacturer and is the sole distributor of that manufacturer’s product to a subsequent repackager, wholesale distributor, or dispenser.

(7) “GRANDFATHERED” means, with respect to a product, a product that is not labeled with a product identifier and that entered the pharmaceutical distribution supply chain on or before March 1, 2016.

(8) “HOMOGENOUS CASE” means a sealed case containing only product that has a single National Drug Code number belonging to a single lot.

(9) “ILLEGITIMATE PRODUCT” means a product that:
   (a) Is counterfeit, diverted, or stolen;
   (b) Is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
   (c) Is the subject of a fraudulent transaction; or
   (d) Appears unfit for distribution such that the product would likely result in serious adverse health consequences or death to humans.

(10) “LICENSED” means having a valid license in accordance with Florida law. For the purposes of Rules 61N-1.028, 61N-1.029, 61N-1.030, 61N-1.031 and 61N-1.032, F.A.C., a dispenser is considered “licensed” if the dispenser has a valid license under Florida law.

(11) “MANUFACTURER” means:
   (a) A person that holds an application approved under 21 U.S.C. § 355 (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06715, or a license issued under section 351 of the Public Health Service Act (42 U.S.C. s. 262) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06716, for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product;
(b) A co-licensed partner or affiliate of a person described in paragraph 61N-1.028(11)(a), F.A.C., that obtains the product directly from a person described in this paragraph or paragraph 61N-1.028(11)(a) or 61N-1.028(11)(c), F.A.C.; or

(c) An affiliate of a person described in paragraph 61N-1.028(11)(a) or 61N-1.028(11)(b), F.A.C., that receives the product directly from a person described in this paragraph or paragraph 61N-1.028(11)(a) or 61N-1.028(11)(b), F.A.C.

(12) “MEDICAL CONVENIENCE KIT” means packages or units that contain combination products as defined in 21 C.F.R. s. 3.2(e)(2) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06712. A “medical convenience kit” is considered an “exempt medical convenience kit” if it is a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user, and:

(a) The kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer in accordance with 21 U.S.C. s. 360(b)(2) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06717;


(c) If the kit includes a product:

1. The person that manufacturers the kit purchased the product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer and did not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and,

2. The product is:
   a. An intravenous solution intended for the replenishment of fluids and electrolytes;
   b. A product intended to maintain the equilibrium of water and minerals in the body;
   c. A product intended for irrigation or reconstitution;
   d. An anesthetic;
   e. An anticoagulant;
   f. A vasopressor; or
   g. A sympathomimetic.

(13) “PACKAGE” means the smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product. For purposes of this paragraph, an “individual saleable unit” is the smallest container of product introduced into commerce by the manufacturer or repackager that is intended by the manufacturer or repackager for individual sale to a dispenser.


(15) “PRODUCT IDENTIFIER” means a standardized graphic that includes, in both human readable form and on a machine-readable data carrier, the standardized numerical identifier, lot number, and expiration date of the product. Unless authorized by the department, the applicable data shall be included in a 2-dimensional data matrix barcode when affixed to, or imprinted upon a package and homogeneous case.

(16) “QUARANTINE” means the storage or identification of a product, to prevent distribution or transfer of the product, in a physically separate area clearly identified for such use.
(17) “REPACKAGER” means a person who owns or operates an establishment that repacks and relabels a product or package for further sale or distribution without a further transaction.

(18) “RETURN” means providing product to the authorized immediate trading partner from which such product was purchased or received, or to a returns processor or reverse logistics provider for handling of such product.

(19) “RETURNS PROCESSOR or REVERSE LOGISTICS PROVIDER” means a person who owns or operates an establishment that dispositions or otherwise processes saleable or nonsaleable product received from an authorized trading partner such that the product may be processed for credit to the purchaser, manufacturer, or seller or disposed of for no further distribution.

(20) “SPECIFIC PATIENT NEED” refers to the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. Such term does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need.

(21) “STANDARDIZED NUMERICAL IDENTIFIER” means a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.

(22) “SUSPECT PRODUCT” means a product for which there is reason to believe that such product:
(a) Is potentially counterfeit, diverted, or stolen;
(b) Is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
(c) Is potentially the subject of a fraudulent transaction; or
(d) Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

(23) “THIRD PARTY LOGISTICS PROVIDER” means an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.

(24) “TRADING PARTNER” means:
(a) A manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product; or
(b) A third-party logistics provider from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct possession of a product.

(25) “TRANSACTION”.
(a) The term “transaction” means the transfer of product between persons in which a change of ownership occurs.
(b) EXEMPTIONS. The term “transaction” does not include:
1. Intracompany distribution of any product between members of an affiliate or within a manufacturer;
2. The distribution of a product among hospitals or other health care entities that are under common control;
3. The distribution of a product for emergency medical reasons including a public health emergency declaration pursuant to section 319 of the Public Health Service Act (42 U.S.C. s. 247d) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06724, except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;
5. The distribution of product samples by a manufacturer or a licensed wholesale distributor in accordance with 21 U.S.C. s. 353(d) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06726.
6. The distribution of blood or blood components intended for transfusion;
7. The distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use;
8. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in 26 U.S.C. s. 501(c)(3) (Internal Revenue Code) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06727, to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
9. The distribution of a product pursuant to the sale or merger of a pharmacy or pharmacies or a wholesale distributor or wholesale distributors, except that any records required to be maintained for the product shall be transferred to the new owner of the pharmacy or pharmacies or wholesale distributor or wholesale distributors;


11. Products transferred to or from any facility that is licensed by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. s. 2021) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06720.

   a. A product comprised of a device and 1 or more other regulated components (such as a drug/device, biologic/device, or drug/device/biologic) that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
   b. 2 or more separate products packaged together in a single package or as a unit and comprised of a drug and device or device and biological product; or
   c. 2 or more finished medical devices plus one or more drug or biological products that are packaged together in a “medical convenience kit”;

13. The distribution of an “exempt medical convenience kit” as set forth in subsection 61N-1.028(12), F.A.C.;

14. The distribution of an intravenous product that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

15. The distribution of an intravenous product used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

16. The distribution of a product that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

17. The distribution of a medical gas (as defined in 21 U.S.C. s. 360ddd) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06721; or


26) “TRANSACTION HISTORY” means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product. The transaction history for a grandfathered product begins with the owner of the product on January 1, 2015.

27) “TRANSACTION INFORMATION” means:
   (a) The proprietary or established name or names of the product;
   (b) The strength and dosage form of the product;
   (c) The National Drug Code number of the product;
   (d) The container size;
   (e) The number of containers;
   (f) The lot number of the product;
   (g) The date of the transaction;
   (h) The date of the shipment, if more than 24 hours after the date of the transaction;
   (i) The business name and address of the person from whom ownership is being transferred; and,
   (j) The business name and address of the person to whom ownership is being transferred.

28) “TRANSACTION STATEMENT” means a statement, in paper or electronic form, that the entity transferring ownership in a transaction:
   (a) Is authorized as required under this chapter;
   (b) Received the product from a person that is authorized as defined in subsection 61N-1.028(2), F.A.C.;
(c) Received transaction information and a transaction statement from the prior owner of the product, as required under Rules 61N-1.028, 61N-1.029, 61N-1.030, 61N-1.031 and 61N-1.032, F.A.C.;
(d) Did not knowingly ship a suspect or illegitimate product;
(e) Had systems and processes in place to comply with verification requirements under Rules 61N-1.028, 61N-1.029, 61N-1.030, 61N-1.031 and 61N-1.032, F.A.C.;
(f) Did not knowingly provide false transaction information; and,
(g) Did not knowingly alter the transaction history.

The owner of a grandfathered product is exempt from asserting receipt of transaction information and transaction statement from the prior owner.

(29) “VERIFICATION” or “VERIFY” means determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager.

(30) “WHOLESALE DISTRIBUTION” means the distribution of a drug subject to 21 U.S.C. s. 353(b) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06723, to a person other than a consumer or patient, or receipt of a drug subject to 21 U.S.C. s. 353(b) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06723, by a person other than the consumer or patient, but does not include:

(a) Intracompany distribution of any drug between members of an affiliate or within a manufacturer;
(b) The distribution of a drug, or an offer to distribute a drug among hospitals or other health care entities which are under common control;
(c) The distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to 42 U.S.C. s. 247d (section 319 of the Public Health Service Act) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06724, except that, for purposes of this paragraph, a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;
(e) The distribution of minimal quantities of drug by a licensed community pharmacy that is a retail pharmacy to a licensed practitioner for office use;
(f) The distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
(g) The purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;
(h) The distribution of a drug by the manufacturer of such drug;
(i) The receipt or transfer of a drug by an authorized third-party logistics provider provided that such third-party logistics provider does not take ownership of the drug;
(j) A common carrier that transports a drug, provided that the common carrier does not take ownership of the drug;
(k) The distribution of a drug, or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repacks it in accordance with 21 U.S.C. s. 360eee-1(e) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06732.
(l) Saleable drug returns when conducted by a dispenser;
(m) The distribution of an “exempt medical convenience kit” as set forth in subsection 61N-1.028(12), F.A.C.;
(n) The distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);
(o) The distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;
(p) The distribution of a drug that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;
(r) Facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments; or
(s) The transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at
the direction of the hospital or other health care entity, to a repackager described in 21 U.S.C. s. 360eee(16)(B) (as of 12/1/15) which
360 (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06731, for the
purpose of repackaging the drug for use by that hospital, or other health care entity and other health care entities that are under
common control, if ownership of the drug remains with the hospital or other health care entity at all times.

(31) “WHOLESALE DISTRIBUTOR” means a person (other than a manufacturer, a manufacturer’s co-licensed partner, a
third-party logistics provider, or repackager) engaged in wholesale distribution.

Rulemaking Authority 499.0121, 499.05 FS. Law Implemented 499.002, 499.0121, 499.05, 499.052 FS. History–New 5-16-16.
61N-1.029 Product Tracking and Tracing – Manufacturer Requirements.

The following tracking and tracing requirements shall apply to manufacturers:

(1) PRODUCT TRACING.

(a) A manufacturer shall, prior to or at the time of each transaction in which such manufacturer transfers ownership of a product:

1. Provide the subsequent owner with transaction history, transaction information, and a transaction statement, in a single document in a paper or electronic format;

2. Capture the transaction information, including lot level information, transaction history, and transaction statement for each transaction; and,

3. Maintain such information, history, and statement for not less than 6 years after the date of the transaction.

(b) Requests For Information. Upon a request by the department, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, a manufacturer shall, not later than 1 business day, and not to exceed 48 hours, after receiving the request, provide the applicable transaction information, transaction history, and transaction statement for the product.

(c) Electronic Format. Effective December 1, 2017, a manufacturer shall provide the transaction information, transaction history, and transaction statement required under paragraph 61N-1.029(1)(a), F.A.C., in an electronic format. A manufacturer may continue to provide the transaction information, transaction history, and transaction statement required under paragraph 61N-1.029(1)(a), F.A.C., in a paper format to a licensed health care practitioner authorized to prescribe medication under Florida law or other licensed individual under the supervision or direction of such a practitioner who dispenses product in the usual course of professional practice.

(d) Product Identifier. Effective December 1, 2017, a manufacturer shall affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction into commerce. Such manufacturer shall maintain the product identifier information for such product for not less than 6 years after the date of the transaction. A package that is required to have a standardized numerical identifier is not required to have a unique device identifier.

(2) AUTHORIZED TRADING PARTNERS. The trading partners of a manufacturer may only be authorized trading partners.

(3) VERIFICATION. The department adopts and incorporates by reference the manufacturer verification requirements as set forth in the federal act at 21 U.S.C. s. 360eee-1(b)(4) http://www.flrules.org/Gateway/reference.asp?No=Ref-06759 (as of 12/1/15). A manufacturer must establish, maintain, and adhere to written policies and procedures setting forth the manner in which the manufacturer will meet the federal verification requirements as adopted by the department.

Rulemaking Authority 499.0121, 499.05 FS. Law Implemented 499.002, 499.0121, 499.05, 499.052 FS. History–New 5-11-16.
61N-1.030 Product Tracking and Tracing – Wholesale Distributor Requirements.

The following tracking and tracing requirements shall apply to wholesale distributors:

(1) PRODUCT TRACING.

(a) A wholesale distributor shall not accept ownership of a product unless the previous owner prior to, or at the time of, the transaction provides the transaction history, transaction information, and a transaction statement for the product, as applicable under this paragraph.

(b) A wholesale distributor that purchased a product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer, shall prior to, or at the time of, each transaction in which the wholesale distributor transfers ownership of a product, provide to the subsequent purchaser:

1. A transaction statement, which shall state that the wholesale distributor, or a member of the affiliate of the wholesale distributor, purchased the product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased the product directly from the manufacturer; and,

2. The transaction history and transaction information.

3. If provided to a dispenser, the transaction history, transaction information, and transaction statement shall be on a single document in a paper or electronic format.

4. If provided to a wholesale distributor, the transaction history, transaction information, and transaction statement shall be through any combination of self-generated paper, electronic data, or manufacturer provided information on the product package.

5. The lot number of the product, the initial transaction date and the initial shipment date from the manufacturer are not required to be included in the transaction history and information for transactions falling under paragraph 61N-1.030(1)(b), F.A.C.

(c) A wholesale distributor that did not purchase a product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer, shall prior to, or at the time of, each transaction or subsequent transaction, provide to the subsequent purchaser, a transaction statement, transaction history, and transaction information, in a paper or electronic format that complies with the requirements set forth in the departmental rules.

1. The transaction history supplied shall begin only with the wholesale distributor that purchased the product directly from the manufacturer, the exclusive distributor of the manufacturer or a repackager that purchased directly from the manufacturer.

2. The wholesale distributor that did not purchase directly from the manufacturer, the exclusive distributor of the manufacturer or a repackager that purchased directly from the manufacturer, shall inform the subsequent purchaser that the wholesale distributor received a direct purchase statement from a wholesale distributor that purchased the product directly from the manufacturer, the exclusive distributor of the manufacturer or a repackager that purchased directly from the manufacturer.

(d) A wholesale distributor shall capture the transaction information, including lot level information, transaction history, and transaction statement for each transaction described in this rule and maintain such information, history, and statement for not less than 6 years after the date of the transaction; and maintain the confidentiality of the transaction information, including any lot level information, transaction history, and transaction statement for a product and prohibit disclosure to any person other than state or federal officials, except to comply with the provisions of Rules 61N-1.028, 61N-1.029, 61N-1.030, 61N-1.031 and 61N-1.032, F.A.C.

(2) RETURNS.

(a) Saleable Returns. Notwithstanding paragraph 61N-1.030(1)(a), F.A.C., the following shall apply:

1. Requirements. Until December 1, 2019, a wholesale distributor may accept returned product from a dispenser or repackager pursuant to the terms and conditions of any agreement between the parties, and notwithstanding paragraph 61N-1.030(1)(b), F.A.C., may distribute the returned product without providing the transaction history. For transactions subsequent to the return, the transaction history of the product shall begin with the wholesale distributor that accepted the returned product, consistent with the requirements of this rule.

2. Enhanced Requirements. Beginning December 1, 2019, a wholesale distributor may accept returned product from a dispenser or repackager only if the wholesale distributor can associate the returned product with the transaction information and transaction statement associated with that product. For all transactions after December 1, 2019, the transaction history, as applicable, of the product shall begin with the wholesale distributor that accepted and verified the returned product.

(b) Nonsaleable Returns. A wholesale distributor may return a nonsaleable product to the manufacturer or repackager, to the wholesale distributor from whom the product was purchased, or to a person acting on behalf of such a person, including a returns processor, without providing the information required under paragraph 61N-1.030(1)(a), F.A.C.
(3) REQUESTS FOR INFORMATION. Upon a request by the department, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, a wholesale distributor shall, not later than 1 business day, and not to exceed 48 hours, after receiving the request, provide the applicable transaction information, transaction history, and transaction statement for the product.

(4) TRADING PARTNER AGREEMENTS. Effective December 1, 2019, a wholesale distributor may disclose the transaction information, including lot level information, transaction history, or transaction statement of a product to the subsequent purchaser of the product, pursuant to a written agreement between such wholesale distributor and such subsequent purchaser. Nothing in this subsection shall be construed to limit the applicability of subsections 61N-1.030(1) through 61N-1.030(3), F.A.C.

(5) PRODUCT IDENTIFIER. Effective December 1, 2019, a wholesale distributor may engage in transactions involving a product only if that product is encoded with a product identifier or grandfathered as defined by subsection 61N-1.028(7), F.A.C., and not required to be encoded with a product identifier.

(6) AUTHORIZED TRADING PARTNERS. The trading partners of a wholesale distributor may only be authorized trading partners.

(7) VERIFICATION. The department adopts and incorporates by reference the wholesale distributor verification requirements as set forth in the federal act at 21 U.S.C. s. 360eee-1(c)(4) [http://www.flrules.org/Gateway/reference.asp?No=Ref-06761](http://www.flrules.org/Gateway/reference.asp?No=Ref-06761) (as of 12/1/15). A wholesale distributor must establish, maintain, and adhere to written policies and procedures setting forth the manner in which the wholesale distributor will meet the federal verification requirements as adopted by the department.

(8) Drop Shipment.

(a) A wholesale distributor that does not physically handle or store product shall be exempt from the provisions of this rule, except the federal notification requirements adopted under subsection 61N-1.030(7), F.A.C., provided that the manufacturer, repackager, or other wholesale distributor that distributes the product to the dispenser by means of a drop shipment for such wholesale distributor includes on the transaction information and transaction history to the dispenser, the contact information of the wholesale distributor and provides the transaction information, transaction history, and transaction statement directly to the dispenser.

(b) Drop shipment by the wholesale distributor to trading partners, other than to a dispenser, is not exempt from the provisions of this rule.

Rulemaking Authority 499.0121, 499.05 FS. Law Implemented 499.002, 499.0121, 499.05, 499.052 FS. History–New 5-11-16.
61N-1.031 Product Tracking and Tracing – Dispenser Requirements.

The following tracking and tracing requirements shall apply to dispensers:

(1) PRODUCT TRACING.

(a) A dispenser shall not accept ownership of a product, unless the previous owner prior to or at the time of the transaction, provides transaction history, transaction information, and a transaction statement;

(b) A dispenser shall, prior to, or at the time of, each transaction in which the dispenser transfers ownership of a product, excluding dispensing to a patient or returns, provide the subsequent owner with transaction history, transaction information, and a transaction statement for the product, except that the requirements of this rule shall not apply to sales by a dispenser to another dispenser to fulfill a specific patient need; and,

(c) A dispenser shall capture transaction information, including lot level information, if provided, transaction history, and transaction statements, as necessary to investigate a suspect product, and maintain such information, history, and statements for not less than 6 years after the transaction.

(2) AGREEMENTS WITH THIRD PARTIES. – A dispenser may enter into a written agreement with a third party, including an authorized wholesale distributor, under which the third party confidentially maintains the transaction information, transaction history, and transaction statements, required to be maintained under this rule, on behalf of the dispenser. If a dispenser enters into such an agreement, the dispenser shall maintain a copy of the written agreement and shall not be relieved of the obligations of a dispenser under this rule.

(3) RETURNS.

(a) Saleable Returns. A dispenser may return a product to the trading partner from which the dispenser obtained the product without providing the information required under paragraph 61N-1.031(1)(b), F.A.C.

(b) Nonsaleable Returns. A dispenser may return a nonsaleable product to the manufacturer or repackager, to the wholesale distributor from whom such product was purchased, to a returns processor, or to a person acting on behalf of such a person without providing the information required under subsection 61N-1.031(1), F.A.C.

(4) REQUESTS FOR INFORMATION. Upon a request by the department, in the event of a recall or for the purpose of investigating a suspect or an illegitimate product, a dispenser shall, not later than 2 business days after receiving the request, provide the applicable transaction information, transaction statement, and transaction history that the dispenser received from the previous owner, which shall not include the lot number of the product, the initial transaction date, or the initial shipment date from the manufacturer unless such information was included in the transaction information, transaction statement, and transaction history provided by the manufacturer or the wholesale distributor to the dispenser. The dispenser may respond to the request by providing the applicable information in either paper or electronic format.

(5) PRODUCT IDENTIFIER. Effective December 1, 2020, a dispenser may engage in transactions involving a product only if the product is encoded with a product identifier or grandfathered, as defined by subsection 61N-1.028(7), F.A.C., and is not required to be encoded with a product identifier.

(6) AUTHORIZED TRADING PARTNERS. The trading partners of a dispenser may be only authorized trading partners.

(7) VERIFICATION. The department adopts and incorporates by reference the dispenser verification requirements as set forth in the federal act at 21 U.S.C. s. 360eee-1(d)(4) [http://www.flrules.org/Gateway/reference.asp?No=Ref-06762 (as of 12/1/15)]. A dispenser must establish, maintain, and adhere to written policies and procedures setting forth the manner in which the dispenser will meet the federal requirements as adopted by the department.

(8) EXCEPTION. Notwithstanding any other provision of law, the requirements under subsections 61N-1.031(1) through (4), and (7), F.A.C., shall not apply to licensed health care practitioners authorized to prescribe or administer medication under Florida law or other licensed individuals under the supervision or direction of practitioners who dispense or administer products in the usual course of professional practice.

Rulemaking Authority 499.0121, 499.05 FS. Law Implemented 499.002, 499.0121, 499.05, 499.052 FS. History–New 5-11-16.
61N-1.032 Product Tracking and Tracing – Repackager Requirements.
The following tracking and tracing requirements shall apply to repackagers:

(1) PRODUCT TRACING.
(a) A repackager shall not accept ownership of a product unless the previous owner, prior to, or at the time of, the transaction, provides transaction history, transaction information, and a transaction statement for the product.
(b) A repackager, prior to, or at the time of, each transaction in which the repackager transfers ownership of a product, shall provide the subsequent owner with transaction history, transaction information, and a transaction statement for the product.
(c) A repackager shall capture the transaction information, including lot level information, transaction history, and transaction statement for each transaction described in paragraphs 61N-1.032(1)(a) and (1)(b), F.A.C., and shall maintain such information, history, and statement for not less than 6 years after the transaction.

(2) RETURNS.
(a) Nonsaleable Product. A repackager may return a nonsaleable product to the manufacturer or repackager, or to the wholesale distributor from whom such product was purchased, or to a person acting on behalf of such manufacturer, repackager or wholesale distributor, including a returns processor, without providing the information required under paragraph 61N-1.032(1)(b), F.A.C.
(b) Saleable or Nonsaleable Product. A repackager may return a saleable or nonsaleable product to the manufacturer, repackager, or to the wholesale distributor from whom the product was received without providing the information required under paragraph 61N-1.032(1)(b), F.A.C., on behalf of the hospital or other health care entity that took ownership of such product pursuant to the terms and conditions of any agreement between such repackager and the entity that owns the product.

(3) REQUESTS FOR INFORMATION. Upon a request by the department, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, a repackager shall, not later than 1 business day, and not to exceed 48 hours, after receiving the request, provide the applicable transaction information, transaction history, and transaction statement for the product.

(4) PRODUCT IDENTIFIER. Beginning December 1, 2018, a repackager shall:
(a) Affix or imprint a product identifier to each package and homogenous case of product intended to be introduced in a transaction in commerce;
(b) Maintain the product identifier information for such product for not less than 6 years after the date of the transaction;
(c) Engage in transactions involving a product only if such product is encoded with a product identifier or grandfathered as defined by subsection 61N-1.028(7), F.A.C., and is not required to be encoded with a product identifier; and,
(d) Maintain records for not less than 6 years.
A repackager is not required to affix or imprint a unique device identifier on a package that is required to have a standardized numerical identifier.

(5) AUTHORIZED TRADING PARTNERS. The trading partners of a repackager may only be authorized trading partners.

(6) VERIFICATION. The department adopts and incorporates by reference the repackager verification requirements as set forth in the federal act at 21 U.S.C. s. 360eee-1(e)(4) http://www.flrules.org/Gateway/reference.asp?No=Ref-06763 (as of 12/1/15). A repackager must establish, maintain, and adhere to written policies and procedures setting forth the manner in which the repackager will meet the federal verification requirements as adopted by the department.

Rulemaking Authority 499.0121, 499.05 FS. Law Implemented 499.002, 499.0121, 499.05, 499.052 FS. History–New 5-11-16.
61N-2.001 Application for Complimentary Drug Distributor Permit.

A complimentary drug distributor permit is required for any person that engages in the distribution of a complimentary drug, subject to the requirements of s. 499.028. A person, prior to engaging in activity for which a complimentary drug distributor permit is required, must file with the department a completed application on form number DBPR-DDC-221, Application for Permit as a Complimentary Drug Distributor, effective April 2016, adopted and incorporated herein by reference and comply with all the requirements for permitting in Chapter 499, F.S. and Rule 61N, F.A.C. This form is available upon request from the Division of Drugs, Devices and Cosmetics at 1940 N. Monroe Street, Tallahassee, Florida 32399, (850) 717-1800, or at https://www.flrules.org/Gateway/reference.asp?No=Ref-06903

Rulemaking Authority 499.012(3), 499.05 FS. Law Implemented 499.01, 499.012, 499.0121, 499.028, 499.04, 499.041 FS.

History--New.
APPLICATION CHECKLIST – IMPORTANT – Submit all items on the checklist below with your application to ensure faster processing.

<table>
<thead>
<tr>
<th>APPLICATION REQUIREMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enclose the fee of $650.00 if located in the state of Florida, which includes $500.00 biennial application fee and $150.00 initial application/on-site inspection fee. If located outside the state of Florida, submit a fee of $500.00.</td>
</tr>
<tr>
<td>Make cashier’s check, corporate or business check, or money order payable to the Florida Department of Business and Professional Regulation.</td>
</tr>
<tr>
<td>If the applicant answered “Yes” to any question in Section IV, enclose a detailed explanation along with any relevant documentation.</td>
</tr>
<tr>
<td>Sign and date the Affidavit section of the application.</td>
</tr>
</tbody>
</table>

Submit the completed application with enclosures to:
Department of Business and Professional Regulation
1940 North Monroe Street
Tallahassee, FL 32399

PLEASE NOTE:
Telephone, email, and fax contact information is used to quickly resolve questions with applications. If such information is not provided, questions regarding applications will be mailed to the application contact’s mailing address and may take longer to resolve.
State of Florida
Department of Business and Professional Regulation
Division of Drugs, Devices, and Cosmetics

Application for Permit as a Complimentary Drug Distributor
Form No.: DBPR-DDC-221

If you have any questions or need assistance in completing this application, please contact the Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics, at 850.717.1800. For additional information see the instructions at the beginning of this application.

Section I – Application Type

CHECK ONE OF THE APPLICATION TYPES

☐ New Application [3340/1020]
☐ New Application due to Change in Ownership. If checked, provide legal documentation for the change of ownership (i.e. Bill of Sale, stock transfer, merger). [3340/1020]

Current Permit Number: ____________________________

Section II – Applicant Information

APPLICANT INFORMATION

TAXPAYER IDENTIFICATION NUMBER OR FEDERAL EMPLOYER IDENTIFICATION NUMBER
This is a unique nine-digit number assigned by the Internal Revenue Service (IRS) to business entities operating in the United States for the purposes of identification. When the number is used for identification rather than employment tax reporting, it is usually referred to as a Taxpayer Identification Number (TIN), and when used for the purposes of reporting employment taxes, it is usually referred to as the Federal Employer Identification Number (EIN).

Applicant’s TIN/FEIN: ____________________________

FULL LEGAL NAME
The “full legal name” is the complete name of the business entity that will be operating the establishment. This is generally the name that is on the documents that establish the existence or formation of the business entity. For example, a corporation’s full legal name would normally be the name that is found in the corporation’s articles of incorporation.

Applicant’s Full Legal Name: ____________________________

FICTIONOUS, TRADE, OR BUSINESS NAME
If the applicant intends to operate the permitted establishment under a name that is different from the Applicant’s Full Legal Name listed above – e.g. fictitious, trade, or business name (also commonly referred to as a “dba”, “DBA”, or “doing business as” name – this name must be registered with the Florida Department of State, Division of Corporations. This is the name that will appear on the permit issued to the applicant by the department and must be the name that the applicant uses on operational documents for permitted activities.

☐ The applicant WILL NOT operate the permitted establishment under a name that is different from the Applicant’s Full Legal Name listed above.

☐ The applicant WILL operate the permitted establishment under the following fictitious, trade, or business name:

The fictitious, trade, or business name listed directly above, is registered with the Florida Department of State, Division of Corporations and the applicant has been issued the following registration number:

__________________________
# Applicant's Mailing Address

Street Address or P.O. Box:  

City:  
State:  
Zip Code (+4 optional):  

# Physical Address of Establishment to Be Permitted

(only if different from mailing address) Check ☐ if not applicable  

Street Address:  

City:  
State:  
Zip Code (+4 optional):  

County (if located in Florida):  
Country:  

E-Mail Address:  
Phone number:  
Fax Number:  

# Application Contact

The application contact is the person that the department will contact if there are questions regarding the responses provided on, or the documentation submitted with, the application. The application contact is also the person that will receive all official communication from the department regarding the application.  

Last/Surname:  
First:  
Middle:  
Suffix:  
Address:  

City:  
State:  
Zip Code (+4 optional):  

Telephone Number:  
Fax Number:  

E-Mail Address:  

# Emergency Contact

The emergency contact is the person that the department will contact in the case of an emergency. During an emergency, the department will contact this person at times outside of the regular business hours listed below. The contact information provided should be sufficient for the department to actually reach and communicate with the person listed in the event of an emergency.  

Last/Surname:  
First:  
Middle:  
Suffix:  

Position/Title:  
Street Address:  

City:  
State:  
Zip Code (+4 optional):  

Phone Number:  
E-Mail Address:  

DBPR-DDC-221 - Application for Permit as a Complimentary Drug Distributor  
Incorporated by rules: 61N-2.001, F.A.C.  
Eff. Date: April 2016  
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Section III – Ownership Information

- **Type of Ownership**
  - [ ] Publicly Held Corporation
  - [ ] Closely Held Corporation
  - [ ] Limited Liability Company
  - [ ] Charitable Organization—501(c)(3)
  - [ ] Sole Proprietorship
  - [ ] Government
  - [ ] Partnership – General
  - [ ] Professional Corporation or Association
  - [ ] Professional Limited Liability Company
  - [ ] Partnership – Other, Including Limited Liability Partnership and Limited Partnership
  - Other: ________

List the state of incorporation or state of organization (except Partnership – General or Sole Proprietorship). Business entities organized under non-U.S. laws list the country of organization.

- [ ] N/A (Partnership – General or Sole Proprietorship)

State or Country:

List name and address of the applicant's registered agent for service of process in Florida (except Sole Proprietorship or Partnership – General) and provide documentation, such as a print out from the Florida Department of State, Division of Corporations' webpage that the applicant’s registered agent is registered with the Florida Department of State, Division of Corporations.

- [ ] N/A (Partnership – General or Sole Proprietorship)

Name:

Address:

City: __________ State: ______ Zip Code (+4 Optional): ________

List the name, position/title, social security number, date of birth and address of each owner, partner, member, manager, officer, director, chief executive, or other person who directly or indirectly controls the operation of the business entity, as applicable. For example, corporations would list officers and directors, limited liability companies would list managers and members, etc.

1. Name & Title: ___________________________ Social Security #: ________ Date of Birth: ________ % of Ownership: ________
   Street Address: __________________________ City: ______ State: ______ Zip Code: ______

2. Name & Title: ___________________________ Social Security #: ________ Date of Birth: ________ % of Ownership: ________
   Street Address: __________________________ City: ______ State: ______ Zip Code: ______

DBPR-DOC-221 - Application for Permit as a Complimentary Drug Distributor
Incorporated by rules 61N-2.001, F.A.C.
Eff. Date: April 2016
Page 4 of 10
<table>
<thead>
<tr>
<th></th>
<th>Name &amp; Title:</th>
<th>Social Security #:</th>
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<th>% of Ownership:</th>
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<th>Social Security #:</th>
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<th>% of Ownership:</th>
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<tr>
<td>8.</td>
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</tbody>
</table>

List the name, social security number, date of birth and address of each person who owns 10 percent or more of the outstanding stock or equity interest in the business entity.

1. Name:
   Social Security #:  
   Date of Birth:  
   % of Ownership:

   Street Address:  
   City:  
   State:  
   Zip Code:

2. Name:
   Social Security #:  
   Date of Birth:  
   % of Ownership:

   Street Address:  
   City:  
   State:  
   Zip Code:

3. Name:
   Social Security #:  
   Date of Birth:  
   % of Ownership:
<table>
<thead>
<tr>
<th>Name:</th>
<th>Social Security #:</th>
<th>Date of Birth:</th>
<th>% of Ownership:</th>
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</table>

Street Address:   City:   State:   Zip Code:

List all trade or business names used by the applicant. Use additional sheet(s) if necessary. If the applicant does not use other trade or business names check this box [ ] and write N/A on the lines below.

Is the applicant a subsidiary of another company? (If yes, provide a listing of all parent companies with percentages of ownership, using additional sheet(s) if necessary). Note: A permit issued pursuant to this application is only valid for the applicant, and the applicant's name and address. (If no, please check this box [ ] and write "N/A" in the lines below).

<table>
<thead>
<tr>
<th>Parent Company Name</th>
<th>% of Ownership</th>
</tr>
</thead>
<tbody>
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Section IV – Background Questions

DBPR-DDC-221 - Application for Permit as a Complimentary Drug Distributor
Incorporated by rules 61N-2.001, F.A.C.
Eff. Date: April 2016
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### BACKGROUND QUESTIONS

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Has the applicant or any &quot;affiliated party&quot; (defined below) been found guilty of (regardless of adjudication), or pled no contendere to, in any jurisdiction, a violation of law that directly relates to a drug, device, or cosmetic? If yes, explain in detail in Section V</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Has the applicant or any affiliated party (defined below) been fined or disciplined by a regulatory agency in any state (including Florida) for any offense that would constitute a violation of Chapter 499, F.S.? If yes, explain in detail in Section V</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Has the applicant or any affiliated party (defined below) been convicted (regardless of adjudication) of any felony under a federal, state (including Florida), or local law? If yes, explain in detail in Section V</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Has the applicant or any affiliated party (defined below) been denied a permit or license in any state (including Florida) related to an activity regulated under Chapters 456, 465, 499, or 893, F.S.? If yes, explain in detail in Section V</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Has the applicant or any affiliated party (defined below) had any current or previous permit or license suspended or revoked which was issued by a federal, state, or local governmental agency relating to the manufacture or distribution of drugs, devices, or cosmetics? If yes, explain in detail in Section V</td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Has the applicant or any affiliated party (defined below) ever held a permit issued under Chapter 499, F.S., in a different name than the applicant's name? (If yes, provide the names in which each permit was issued and at what address.) If yes, explain in detail in Section V</td>
<td></td>
</tr>
</tbody>
</table>

The term "affiliated party" means: (a) a director, officer, trustee, partner, or committee member of a permittee or applicant or a subsidiary or service corporation of the permittee or applicant; (b) a person who, directly or indirectly, manages, controls, or oversees the operation of a permittee or applicant, regardless of whether such person is a partner, shareholder, manager, member, officer, director, independent contractor, or employee of the permittee or applicant; (c) a person who has filed or is required to file a personal information statement pursuant to s. 499.012(9) or is required to be identified in an application for a permit or to renew a permit pursuant to s. 499.012(8); or (d) the five largest natural shareholders that own at least 5 percent of the permittee or applicant.

If you answered "YES" to any questions in Section IV, you must provide detailed explanations in Section V, including requirements for submitting supporting legal documents. If needed, explain on separate sheet(s).

### Section V – Explanation(s) for “Yes” response(s) to background question(s) in Section IV

<table>
<thead>
<tr>
<th>EXPLANATION</th>
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DBPR-DDC-221 - Application for Permit as a Complimentary Drug Distributor
Incorporated by rules: 61N-2.001, F.A.C.
Eff. Date: April 2016
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Section VI – Other Permits or Licenses

<table>
<thead>
<tr>
<th>PERMITS OR LICENSES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Are there any other permits or licenses issued by any agency of the State of Florida that authorize the purchase or possession of prescription drugs at the applicant's establishment or address? (If no, please check this box □ and write &quot;N/A&quot; in the lines below).</td>
</tr>
<tr>
<td>□ Yes □ No</td>
</tr>
<tr>
<td>1a. Permit/License Name</td>
</tr>
<tr>
<td>-------------------------</td>
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</tbody>
</table>

Section VII – Complimentary Prescription Drug Distribution Activity

<table>
<thead>
<tr>
<th>DISTRIBUTION ACTIVITIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify the types of products the applicant will distribute under this permit. Check all that apply.</td>
</tr>
<tr>
<td>□ Human Prescription Drugs</td>
</tr>
<tr>
<td>□ Solid Dose</td>
</tr>
<tr>
<td>□ Liquids (Oral)</td>
</tr>
<tr>
<td>□ Injectables</td>
</tr>
<tr>
<td>□ Topical</td>
</tr>
<tr>
<td>□ Dental</td>
</tr>
</tbody>
</table>

Controlled Substances: Provide your DEA Number: ____________ or check □ No DEA Number

Check Schedules: □ Sch II □ Sch III □ Sch IV □ Sch V
1. Are products to be distributed under this permit intended for export? (Note: A permit may be required for freight forwarders handling products in Florida.)
   □ Yes □ No

2. Will all required records be stored and maintained at applicant’s physical address? (If no, provide the address of the establishments where all required records will be stored and maintained under question #3).
   □ Yes □ No

3. Physical address where required records will be stored:
   City: __________________________
   Street Address: __________________________
   State: __________________________
   Zip Code (+4 optional): __________________________

4. Will the required records be computerized, automated or stored electronically? If yes, will you have a back-up procedure to be able to provide required records?
   □ Yes □ No

5. Does the applicant understand that as a complimentary drug distributor you can only distribute drug samples to practitioners licensed to prescribe and dispense prescription drugs, or at the request of a practitioner, to pharmacies of hospitals or pharmacies of other health care entities?
   □ Yes □ No

6. Is the establishment you are seeking to permit outside of the State of Florida? If yes, you must provide a copy of a valid license or permit issued by the State or U.S. Territory in which the establishment resides which authorizes the distribution of prescription drugs from the physical location of the establishment you are seeking to permit.
   License Number: __________________________
   Expiration Date: __________________________
   Copy attached? □ Yes □ No □ N/A

7. How are your drug samples distributed?
   □ Mail
   □ Representative in Florida
   □ Other – Please explain; use another sheet of paper if necessary.

8. Does the applicant use a fulfillment house, shipping and mailing service, or distribute through co-marketing agreements? If yes, please provide the:
   Contractor’s name:
   Contractor’s address:
   Contractor’s responsibilities:

9. Distributors must have a policy that addresses the return of prescription drugs. Provide a copy of your company’s “Return Policy” for prescription drug samples.
   Copy attached? □ Yes □ No

10. If located in the State of Florida, provide the date the establishment will be ready and available for inspection. This is the earliest date the application may be deemed complete.
    __/__/20
Section VIII – Affidavit

AFFIDAVIT

Pursuant to s. 559.79, F.S., each application for a license or renewal of a license issued by the Department of Business and Professional Regulation shall be signed under oath or affirmation by the applicant, or owner or chief executive of the applicant without the need for witnesses unless otherwise required by law.

Pursuant to s. 559.791, F.S., any license issued by the Department of Business and Professional Regulation which is issued or renewed in response to an application upon which the person signing under oath or affirmation has falsely sworn to a material statement, including, but not limited to, the names and addresses of the owners or managers of the licensee or applicant, shall be subject to denial of the application or suspension or revocation of the license, and the person falsely swearing shall be subject to any other penalties provided by law.

I UNDERSTAND THAT THE ISSUANCE OF A PERMIT BY THE DEPARTMENT ONLY AUTHORIZES THE APPLICANT TO CONDUCT REGULATED ACTIVITIES IN THE STATE OF FLORIDA UNDER THE NAME IN WHICH THE PERMIT IS ISSUED. IF THE PERMIT IS ISSUED IN THE NAME OF A DBA OR D/B/A THE APPLICANT MAY ONLY CONDUCT BUSINESS IN FLORIDA IN THE NAME OF THE DBA OR D/B/A.

I FURTHER UNDERSTAND THAT PROVIDING ADDITIONAL DBA OR D/B/A NAMES TO THE DEPARTMENT AS PART OF THE APPLICATION PROCESS IS NOT, UPON LICENSURE, AN AUTHORIZATION TO CONDUCT BUSINESS IN FLORIDA UNDER THE NAME OF THOSE ADDITIONAL DBA’S OR D/B/A’S.

I certify that I am empowered to execute this application as required by s. 559.79, F.S. I understand that my signature on this application has the same legal effect as if made under oath. To the best of my knowledge, all information contained on this application is true and correct. I understand the falsification of any information on this application may result in administrative action, including a fine, suspension, or revocation of the license.

Signature of Applicant, Owner or Chief Executive: Date:

Print Name: Title:

Mail completed application to:

Department of Business and Professional Regulation
1940 North Monroe Street
Tallahassee, FL 32399
61N-2.002 Application for Cosmetic Manufacturer Permit

A cosmetic manufacturer permit is required for any person that manufactures or repackages cosmetics in this state. A person that only labels or changes the labeling of a cosmetic but does not open the container sealed by the manufacturer of the product is exempt from obtaining a permit. A person located in this state, prior to engaging in activity for which a cosmetic manufacturer permit is required, must file with the department a completed application on form number DBPR-DDC-206, Application for Permit as a Cosmetic Manufacturer, effective April 2016, adopted and incorporated herein by reference and comply with all the requirements for permitting in Chapter 499, F.S. and Rule 61N, F.A.C. This form is available upon request from the Division of Drugs, Devices and Cosmetics at 1940 N. Monroe Street, Tallahassee, Florida 32399, (850) 717-1800, or at http://www.flrules.org/Gateway/reference.asp?No=Ref-06904

Rulemaking Authority 499.012(3) F.S. Law Implemented 499.01, 499.012, 499.0121, 499.015, 499.04, 499.041 F.S. History–New
APPLICATION CHECKLIST – IMPORTANT – Submit all items on the checklist below with your application to ensure faster processing.

<table>
<thead>
<tr>
<th>APPLICATION</th>
<th>APPLICATION REQUIREMENTS</th>
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<tbody>
<tr>
<td>Application for Permit as a Cosmetic Manufacturer</td>
<td>□ Submit fee of $950.00, which includes $800.00 biennial application fee and $150.00 initial application/on-site inspection fee. If establishment is applying for multiple manufacturing permits in the applicant's name and at applicant's address, you are only required to pay for the permit with the highest fee.</td>
</tr>
<tr>
<td></td>
<td>□ Make cashier's check, corporate or business check, or money order payable to the Florida Department of Business and Professional Regulation.</td>
</tr>
<tr>
<td></td>
<td>□ If you answer “Yes” to any question in Section IV, be sure to provide a detailed explanation along with any relevant documentation.</td>
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<tr>
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<td>□ Sign and date the Affidavit section of the application.</td>
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<tr>
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<td>Submit the completed application with enclosures to:</td>
</tr>
<tr>
<td></td>
<td>Department of Business and Professional Regulation</td>
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<tr>
<td></td>
<td>1940 North Monroe Street</td>
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<td></td>
<td>Tallahassee, FL 32399</td>
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</tbody>
</table>

PLEASE NOTE:
Telephone, email, and fax contact information is used to quickly resolve questions with applications. If such information is not provided, questions regarding applications will be mailed to the application contact's mailing address and may take longer to resolve.
State of Florida  
Department of Business and Professional Regulation  
Division of Drugs, Devices, and Cosmetics

Application for Permit as a Cosmetic Manufacturer  
Form No.: DBPR-DDC-206

If you have any questions or need assistance in completing this application, please contact the Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics, at 850.717.1800. For additional information see the instructions at the beginning of this application.

Section I – Application Type

<table>
<thead>
<tr>
<th>CHECK ONE OF THE APPLICATION TYPES</th>
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<tbody>
<tr>
<td>☐ New Application [3306/1020]</td>
</tr>
<tr>
<td>☐ New Application due to change in ownership. If checked, provide legal documentation for the change of ownership (i.e. Bill of Sale, stock transfer, merger). [3306/1020]</td>
</tr>
<tr>
<td>Current Permit Number:</td>
</tr>
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</table>

Section II – Applicant Information

APPLICANT INFORMATION

TAXPAYER IDENTIFICATION NUMBER OR FEDERAL EMPLOYER IDENTIFICATION NUMBER

This is a unique nine-digit number assigned by the Internal Revenue Service (IRS) to business entities operating in the United States for the purposes of identification. When the number is used for identification rather than employment tax reporting, it is usually referred to as a Taxpayer Identification Number (TIN), and when used for the purposes of reporting employment taxes, it is usually referred to as the Federal Employer Identification Number (FEIN).

Applicant’s TIN/FEIN: ______________________

FULL LEGAL NAME

The “full legal name” is the complete name of the business entity that will be operating the establishment. This is generally the name that is on the documents that establish the existence or formation of the business entity. For example, a corporation’s full legal name would normally be the name that is found in the corporation’s articles of incorporation.

Applicant’s Full Legal Name: ______________________

FICTITIOUS, TRADE, OR BUSINESS NAME

If the applicant intends to operate the permitted establishment under a name that is different from the Applicant’s Full Legal Name listed above – e.g. fictitious, trade, or business name (also commonly referred to as a “dba”, “D/B/A”, or “doing business as” name – this name must be registered with the Florida Department of State, Division of Corporations. This is the name that will appear on the permit issued to the applicant by the department and must be the name that the applicant uses on operational documents for permitted activities.

☐ The applicant WILL NOT operate the permitted establishment under a name that is different from the Applicant’s Full Legal Name listed above.

☐ The applicant WILL operate the permitted establishment under the following fictitious, trade, or business name: ______________________

The fictitious, trade, or business name listed directly above, is registered with the Florida Department of State, Division of Corporations and the applicant has been issued the following registration number: ______________________
## APPLICANT'S MAILING ADDRESS

<table>
<thead>
<tr>
<th>Street Address or P.O. Box:</th>
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<tbody>
<tr>
<td><strong>City:</strong></td>
<td><strong>State:</strong></td>
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</table>

## PHYSICAL ADDRESS OF ESTABLISHMENT TO BE PERMITTED
(only if different from mailing address) Check ☐ if not applicable

<table>
<thead>
<tr>
<th>Street Address:</th>
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<tbody>
<tr>
<td><strong>City:</strong></td>
<td><strong>State:</strong></td>
</tr>
<tr>
<td><strong>County (if located in Florida):</strong></td>
<td><strong>Country:</strong></td>
</tr>
<tr>
<td><strong>E-Mail Address:</strong></td>
<td><strong>Phone Number:</strong></td>
</tr>
</tbody>
</table>

## APPLICATION CONTACT

The application contact is the person that the department will contact if there are questions regarding the responses provided on, or the documentation submitted with, the application. The application contact is also the person that will receive all official communication from the department regarding the application.

<table>
<thead>
<tr>
<th>Last/Surname:</th>
<th>First:</th>
<th>Middle:</th>
<th>Suffix:</th>
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<tbody>
<tr>
<td><strong>Address:</strong></td>
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<td><strong>City:</strong></td>
<td><strong>State:</strong></td>
<td><strong>Zip Code (+4 optional):</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Telephone Number:</strong></td>
<td><strong>Fax Number:</strong></td>
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</tr>
<tr>
<td><strong>E-Mail Address:</strong></td>
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## EMERGENCY CONTACT INFORMATION

The emergency contact is the person that the department will contact in the case of an emergency. During an emergency, the department will contact this person at times outside of the regular business hours listed below. The contact information provided should be sufficient for the department to actually reach and communicate with the person listed in the event of an emergency.

<table>
<thead>
<tr>
<th>Last/Surname:</th>
<th>First:</th>
<th>Middle:</th>
<th>Suffix:</th>
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<tbody>
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<td><strong>Position/Title:</strong></td>
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<td><strong>State:</strong></td>
<td><strong>Zip Code (+4 optional):</strong></td>
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<tr>
<td><strong>Telephone Number:</strong></td>
<td><strong>E-Mail Address:</strong></td>
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</table>
### OPERATING HOURS

List the establishment's daily hours of operation in terms of Eastern Time. REMEMBER to circle "a.m." or "p.m." for each time indicated below.

<table>
<thead>
<tr>
<th>Day</th>
<th>a.m./p.m. to a.m./p.m.</th>
<th>Fri</th>
<th>a.m./p.m. to a.m./p.m.</th>
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<tr>
<td>Mon</td>
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<td>Sun</td>
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</tbody>
</table>

### Section III – Ownership Information

#### TYPE OF OWNERSHIP

- [ ] Publicly Held Corporation
- [ ] Closely Held Corporation
- [ ] Limited Liability Company
- [ ] Charitable Organization—501(c)(3)
- [ ] Sole Proprietorship
- [ ] Government
- [ ] Partnership – General
- [ ] Professional Corporation or Association
- [ ] Professional Limited Liability Company
- [ ] Partnership – Other, Including Limited Liability Partnership and Limited Partnership

- [ ] Other: ____________________
- [ ] N/A (Partnership – General or Sole Proprietorship)

List the state of incorporation or state of organization (except Partnership – General or Sole Proprietorship). Business entities organized under non-U.S. laws list the country of organization.

- [ ] N/A (Partnership – General or Sole Proprietorship)

#### State or Country:

- Name:
- Address:
- City: ____________________ State: ______ Zip Code: ______

List the name, position/title, social security number, date of birth and address of each owner, partner, member, manager, officer, director, chief executive, or other person who directly or indirectly controls the operation of the business entity, as applicable. For example, corporations would list officers and directors, limited liability companies would list members and managers, etc.

<table>
<thead>
<tr>
<th>Name &amp; Title:</th>
<th>Social Security #:</th>
<th>Date of Birth:</th>
<th>% of Ownership:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
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</table>

<table>
<thead>
<tr>
<th>Name &amp; Title:</th>
<th>Social Security #:</th>
<th>Date of Birth:</th>
<th>% of Ownership:</th>
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<tbody>
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</tbody>
</table>

List the name, social security number, date of birth and address of each person who owns 10 percent or more of the outstanding stock or equity interest in the business entity.

<table>
<thead>
<tr>
<th></th>
<th>Street Address:</th>
<th>City:</th>
<th>State:</th>
<th>Zip Code:</th>
<th>Name:</th>
<th>Social Security #:</th>
<th>Date of Birth:</th>
<th>% of Ownership:</th>
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<td></td>
<td>Name:</td>
<td>Social Security #:</td>
<td>Date of Birth:</td>
<td>% of Ownership:</td>
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</tbody>
</table>

List all trade or business names used by the applicant. Use additional sheet(s) if necessary. If the applicant does not use other trade or business names check this box ☐ and write N/A on the lines below.

Is the applicant a subsidiary of another company? (If yes, provide a listing of all parent companies with percentages of ownership, using additional sheet(s) if necessary).

☐ Yes  ☐ No

Note: A permit issued pursuant to this application is only valid for the applicant, and the applicant's name and address. (If no, please check this box ☐ and write "N/A" in the lines below).

<table>
<thead>
<tr>
<th>Parent Company Name</th>
<th>% of Ownership</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>
### Section IV – Background Questions

#### BACKGROUND QUESTIONS

<table>
<thead>
<tr>
<th>#</th>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Has the applicant or any “affiliated party” (defined below) been found guilty of (regardless of adjudication), or pled no contendere to, in any jurisdiction, a violation of law that directly relates to a drug, device, or cosmetic?</td>
<td>☐</td>
<td>☑</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Has the applicant or any affiliated party (defined below) been fined or disciplined by a regulatory agency in any state (including Florida) for any offense that would constitute a violation of Chapter 499, F.S.?</td>
<td>☐</td>
<td>☑</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Has the applicant or any affiliated party (defined below) been convicted (regardless of adjudication) of any felony under a federal, state (including Florida), or local law?</td>
<td>☐</td>
<td>☑</td>
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</tr>
<tr>
<td>4</td>
<td>Has the applicant or any affiliated party (defined below) been denied a permit or license in any state (including Florida) related to an activity regulated under Chapters 456, 465, 499, or 893, F.S.?</td>
<td>☐</td>
<td>☑</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Has the applicant or any affiliated party (defined below) had any current or previous permit or license suspended or revoked which was issued by a federal, state, or local governmental agency relating to the manufacture or distribution of drugs, devices, or cosmetics?</td>
<td>☐</td>
<td>☑</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Has the applicant or any affiliated party (defined below) ever held a permit issued under Chapter 499, F.S., in a different name than the applicant’s name? (If yes, provide the names in which each permit was issued and at what address).</td>
<td>☐</td>
<td>☑</td>
<td></td>
</tr>
</tbody>
</table>

The term “affiliated party” means: (a) a director, officer, trustee, partner, or committee member of a permittee or applicant or a subsidiary or service corporation of the permittee or applicant; (b) a person who, directly or indirectly, manages, controls, or oversees the operation of a permittee or applicant, regardless of whether such person is a partner, shareholder, manager, member, officer, director, independent contractor, or employee of the permittee or applicant; (c) a person who has filed or is required to file a personal information statement pursuant to s. 499.012(9) or is required to be identified in an application for a permit or to renew a permit pursuant to s. 499.012(8); or (d) the five largest natural shareholders that own at least 5 percent of the permittee or applicant.

If you answered “YES” to any questions in Section IV, you must provide detailed explanations in Section V, including requirements for submitting supporting legal documents. If needed, explain on separate sheet(s).

#### Section V – Explanation(s) for “Yes” response(s) to background question(s) in Section IV

<table>
<thead>
<tr>
<th>EXPLANATION(S)</th>
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</table>

DBPR-DOC-206 - Application for Permit as a Cosmetic Manufacturer
Incorporated by rule: 61N-2.002, F.A.C.
Eff. Date: April 2016
Page 7 of 10
Section VI – Other Permits or Licenses

<table>
<thead>
<tr>
<th>PERMITS OR LICENSES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Are there any other permits or licenses issued by any agency of the State of Florida that authorize the purchase or possession of prescription drugs at the applicant's establishment or address? (If no, please check this box ☐ and write &quot;N/A&quot; in the lines below).</td>
</tr>
<tr>
<td>1a. Permit/License Name</td>
</tr>
<tr>
<td>______________________</td>
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<tr>
<td>______________________</td>
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<tr>
<td>______________________</td>
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</tbody>
</table>

Section VII – Cosmetic Manufacturing Activity

Identify type of operation.

☐ Mixing ☐ Repackaging ☐ Final Labeling for Distribution

Provide your Federal Food and Drug Administration (FDA) establishment registration number.

☐ FDA Establishment Registration Number: ____________________________

or

☐ No FDA Establishment Number

1. Are products to be distributed under this permit intended for export? ☐ Yes ☐ No

2. Will all required records be stored and maintained at applicant's physical address? (If no, provide the address of the establishments where all required ☐ Yes ☐ No
2a Physical address where required records will be stored
Street Address:

<table>
<thead>
<tr>
<th>City:</th>
<th>State:</th>
<th>Zip Code (+4 optional):</th>
</tr>
</thead>
</table>

3. Will the required records be computerized, automated or stored electronically? If yes, will you have a back-up procedure to be able to provide required records?
   - Yes ☐ No ☐

4. Are you submitting a product registration application and labels of your products with this application? (If no, explain on a separate sheet providing accurate details).
   - Yes ☐ No ☐
   **Note:** You CAN NOT SELL a product that you manufacture at the establishment until that product has been registered with the department. Selling a product before it is registered with the division is the basis for application permit denial and enforcement action by the division.
   - Explanation included? Yes ☐ No ☐ N/A

5. Do you have labels of your products ready for inspection?
   - Yes ☐ No ☐

6. Do you manufacture a product that has a sunscreen (SPF)? (If yes, an Over-the-Counter Drug Manufacturer permit is required).
   - Yes ☐ No ☐

7. Do you intend to comply with all Federal and State “Current Good Manufacturing Practices”?* 
   - Yes ☐ No ☐

8. Does the applicant have written policies and procedures to include: water monitoring and testing, manufacturing and control standards for formulations, processing, and packaging, laboratory controls including sample testing, internal auditing, handling complaints and facilitating product recalls?
   - Yes ☐ No ☐
   - Explanation attached? Yes ☐ No ☐ N/A
   (If no, provide written explanation for lack of specific policy or procedure identified above).

9. Rule 61N-1.010, F.A.C., effective July 5, 2015, sets forth the requirements for manufacturing cosmetics. Has the applicant or an employee of the applicant obtained a copy, reviewed and familiarized themself with the requirements set forth in Rule 61N-1.010, F.A.C.? If not, it is recommended that they do so as the standards that will be applied to the applicant’s establishment are set forth in Rule 61N-1.010, F.A.C., and failure to comply with the rule is the basis for permit application denial and enforcement action by the department.
   - Yes ☐ No ☐

10. Provide the date the establishment will be ready and available for inspection. This is the earliest date the application may be deemed complete.
    - /___/20___

---

*DBPR-DDC-206 - Application for Permit as a Cosmetic Manufacturer
Incorporated by rule: 61N-2.002, F.A.C.
Eff. Date: April 2016
Page 9 of 10
Pursuant to s. 559.79, F.S., each application for a license or renewal of a license issued by the Department of Business and Professional Regulation shall be signed under oath or affirmation by the applicant, or owner or chief executive of the applicant without the need for witnesses unless otherwise required by law.

Pursuant to s. 559.791, F.S., any license issued by the Department of Business and Professional Regulation which is issued or renewed in response to an application upon which the person signing under oath or affirmation has falsely sworn to a material statement, including, but not limited to, the names and addresses of the owners or managers of the licensee or applicant, shall be subject to denial of the application or suspension or revocation of the license, and the person falsely swearing shall be subject to any other penalties provided by law.

I UNDERSTAND THAT THE ISSUANCE OF A PERMIT BY THE DEPARTMENT ONLY AUTHORIZES THE APPLICANT TO CONDUCT REGULATED ACTIVITIES IN THE STATE OF FLORIDA UNDER THE NAME IN WHICH THE PERMIT IS ISSUED. IF THE PERMIT IS ISSUED IN THE NAME OF A DBA OR D/B/A THE APPLICANT MAY ONLY CONDUCT BUSINESS IN FLORIDA IN THE NAME OF THE DBA OR D/B/A.

I FURTHER UNDERSTAND THAT PROVIDING ADDITIONAL DBA OR D/B/A NAMES TO THE DEPARTMENT AS PART OF THE APPLICATION PROCESS IS NOT, UPON LICENSURE, AN AUTHORIZATION TO CONDUCT BUSINESS IN FLORIDA UNDER THE NAME OF THOSE ADDITIONAL DBA’S OR D/B/A’S.

I certify that I am empowered to execute this application as required by s. 559.79, F.S. I understand that my signature on this application has the same legal effect as if made under oath. To the best of my knowledge, all information contained on this application is true and correct. I understand the falsification of any information on this application may result in administrative action, including a fine, suspension, or revocation of the license.

Signature of Applicant, Owner or Chief Executive:  
Date:

Print Name:  
Title:

Mail completed application to:

Department of Business and Professional Regulation  
1940 North Monroe Street  
Tallahassee, FL 32399
61N-2.004 Application for Diethyl Ether Manufacturer, Distributor, Dealer or Purchaser Permit

Any person who manufactures, distributes, or deals in ether in this state must possess a current valid license issued by the department, except that a manufacturer, distributor, or dealer who also purchases ether in this state shall not be required to obtain an additional permit as a purchaser of ether. A person, prior to engaging in activity for which a diethyl ether manufacturer, distributor, dealer, or purchaser permit is required, must file with the department a completed application on form number DBPR-DDC-233, Application for Permit as a Diethyl Ether Manufacturer, Distributor, Dealer or Purchaser, effective April 2016, adopted and incorporated herein by reference and comply with all the requirements for permitting in Chapter 499, F.S. and Rule 61N, F.A.C. This form is available upon request from the Division of Drugs, Devices and Cosmetics at 1940 N. Monroe Street, Tallahassee, Florida 32399, (850) 717-1800, or at http://www.flrules.org/Gateway/reference.asp?No=Ref-06905

Rulemaking Authority 499.63, 499.701 FS, Law Implemented 499.62, 499.63, 499.64, 499.66, 499.67 FS. History–New.
State of Florida
Department of Business and Professional Regulation
Division of Drugs, Devices, and Cosmetics

Application for Permit as a Diethyl Ether Manufacturer, Distributor, Dealer, or Purchaser
Form No.: DBPR-DDC-233

APPLICATION CHECKLIST – IMPORTANT – Submit all items on the checklist below with your application to ensure faster processing.

<table>
<thead>
<tr>
<th>APPLICATION</th>
<th>APPLICATION REQUIREMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application for Permit as a Diethyl Ether Manufacturer, Distributor, Dealer, or Purchaser.</td>
<td></td>
</tr>
<tr>
<td>Select the type of ether permit applying for:</td>
<td></td>
</tr>
<tr>
<td>☐ Manufacturer</td>
<td>☐ Manufacturer – Submit fee of $700.00.</td>
</tr>
<tr>
<td>☐ Distributor</td>
<td>☐ Distributor – Submit fee of $700.00.</td>
</tr>
<tr>
<td>☐ Dealer</td>
<td>☐ Dealer – Submit fee of $350.00.</td>
</tr>
<tr>
<td>☐ Purchaser</td>
<td>☐ Purchaser – Submit fee of $150.00.</td>
</tr>
<tr>
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<td>☐ Payment – Make cashier’s check, corporate or business check, or money order payable to the Florida Department of Business and Professional Regulation.</td>
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<tr>
<td></td>
<td>☐ If the applicant answered “Yes” to any question in Section IV, enclose a detailed explanation along with any relevant documentation.</td>
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<tr>
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<td>☐ Sign and date the Affidavit section of the application.</td>
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<tr>
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<td>☐ Attach two 2” X 2” front-view, full face photographs of the owner or chief executive officer, taken within the last six months. These photographs must be clear and recognizable and cannot be on home Polaroid type paper.</td>
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<tr>
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<td>☐ A complete set of fingerprints of any new applicant must be submitted on the fingerprint card issued by the department and must be taken by an authorized law enforcement officer.</td>
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<tr>
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<td>Submit the completed application with enclosures to:</td>
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<td>Department of Business and Professional Regulation</td>
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<tr>
<td></td>
<td>1940 North Monroe Street</td>
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<tr>
<td></td>
<td>Tallahassee, FL 32399</td>
</tr>
</tbody>
</table>

PLEASE NOTE:
Telephone, email, and fax contact information is used to quickly resolve questions with applications. If such information is not provided, questions regarding application will be mailed to the application contact’s mailing address and may take longer to resolve.
GENERAL INFORMATION

Florida law generally defines “establishment” to mean a place of business at one general physical location. As used in this application, “the establishment” refers to the physical address of the establishment to be permitted.

A permit is not required of any person who purchases ether in quantities of less than 2.5 gallons, or equivalent by weight. Any person, who manufactures, distributes, or deals in ether in this state at or from more than one location must possess a current valid license at each location. Only one ether permit is required for each location if multiple activities relating to ether occur at one location, but the highest fee applicable to the operation in each location shall be paid by the applicant.

Ether licenses and permits are valid beginning on October 1 of the year for which they are issued and expire on the following September 30. A licensed or permitted facility shall renew its license or permit prior to its expiration date. If a renewal application and fee are not postmarked by the expiration date, the permit may be reinstated only upon payment of a delinquent fee of $50.00, in addition to the required renewal fee, within 30 days after the date of expiration.

DEFINITIONS:

"Dealer" means any person, firm, corporation, or other entity selling, brokering, or transferring ether to anyone other than a licensed ether manufacturer, distributor, or dealer. This includes selling, brokering, or transferring ether to an exempted facility or to an ether purchaser.

"Distributor" means any person, firm, corporation, or other entity distributing, selling, marketing, transferring, or otherwise supplying ether to retailers, dealers, or any other entity in the primary channel of trade, but does not include retailers.

"Manufacturer" means any person, firm, corporation, or other entity preparing, deriving, producing, synthesizing, or otherwise making ether in any form or repackaging, relabeling, or manipulating ether.

"Purchaser" means any person, firm, corporation, or other entity who purchases ether in quantities of 2.5 gallons, or equivalent by weight, or more for any purpose whatsoever, but does not include a dealer, distributor, or manufacturer.

"Officers of the corporation" mean the five highest corporate officers of the corporation. These generally include the president, vice president, chairman of the board, secretary, treasurer, or equivalent positions.
State of Florida  
Department of Business and Professional Regulation  
Division of Drugs, Devices, and Cosmetics  

Application for Permit as a Diethyl Ether Manufacturer, Distributor, Dealer, or Purchaser  
Form No.: DBPR-DDC-233

If you have any questions or need assistance in completing this application, please contact the Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics, at 850.717.1800. For additional information see the instructions at the beginning of this application.

Section I – Application Type

<table>
<thead>
<tr>
<th>CHECK ONE OF THE APPLICATION TYPES</th>
</tr>
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<tbody>
<tr>
<td>☐ New Application [3310/1020]</td>
</tr>
<tr>
<td>☐ New Application due to change in ownership. If checked, provide legal documentation for the change of ownership (i.e. Bill of Sale, stock transfer, merger). [3310/1020]</td>
</tr>
<tr>
<td>Current Permit Number: __________________________</td>
</tr>
</tbody>
</table>

Section II – Applicant Information

<table>
<thead>
<tr>
<th>APPLICANT INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAXPAYER IDENTIFICATION NUMBER OR FEDERAL EMPLOYER IDENTIFICATION NUMBER</td>
</tr>
<tr>
<td>This is a unique nine-digit number assigned by the Internal Revenue Service (IRS) to business entities operating in the United States for the purposes of identification. When the number is used for identification rather than employment tax reporting, it is usually referred to as a Taxpayer Identification Number (TIN), and when used for the purposes of reporting employment taxes, it is usually referred to as the Federal Employer Identification Number (FEIN).</td>
</tr>
<tr>
<td>Applicant's TIN/FEIN: __________________________</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>FULL LEGAL NAME</th>
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<tr>
<td>The &quot;full legal name&quot; is the complete name of the business entity that will be operating the establishment. This is generally the name that is on the documents that establish the existence or formation of the business entity. For example, a corporation's full legal name would normally be the name that is found in the corporation's articles of incorporation.</td>
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<tr>
<td>Applicant's Full Legal Name: __________________________</td>
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</table>

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<tr>
<th>FICTITIOUS, TRADE, OR BUSINESS NAME</th>
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<tbody>
<tr>
<td>If the applicant intends to operate the permitted establishment under a name that is different from the Applicant's Full Legal Name listed above – e.g. fictitious trade or business name, also commonly referred to as a &quot;dba&quot;, &quot;DBA&quot;, or &quot;doing business as&quot; name – this name must be registered with the Florida Department of State, Division of Corporations. This is the name that will appear on the permit issued to the applicant by the department and must be the name that the applicant uses on operational documents for permitted activities.</td>
</tr>
<tr>
<td>☐ The applicant WILL NOT operate the permitted establishment under a name that is different from the Applicant's Full Legal Name listed above.</td>
</tr>
<tr>
<td>☐ The applicant WILL operate the permitted establishment under the following fictitious, trade, or business name: __________________________</td>
</tr>
</tbody>
</table>

The fictitious, trade, or business name listed directly above, is registered with the Florida Department of State, Division of Corporations and the applicant has been issued the following registration number: __________________________
APPLICANT'S MAILING ADDRESS

Street Address or P.O. Box:

City: State: Zip Code (+4 optional):

PHYSICAL ADDRESS OF ESTABLISHMENT TO BE PERMITTED
(only if different from mailing address) Check [] if not applicable

Street Address:

City: State: Zip Code (+4 optional):

County (if located in Florida): Country:

E-Mail Address: Telephone Number: Fax Number:

OWNER OR CHIEF EXECUTIVE OFFICER (This person must submit photograph and fingerprint)

Last/Surname: First: Middle: Suffix:

Position/Title:

Residence Street Address (must be different than establishment physical address):

City: State: Zip Code (+4 optional):

Residence Phone Number: E-Mail Address:

Social Security Number: Date of Birth: Place of Birth:

Race: Sex: Height:

Weight: Hair Color: Eye Color:

OPERATING HOURS

List Operating Hours. REMEMBER to circle "a.m." or "p.m." for each time indicated below.

Mon: a.m./p.m. to a.m./p.m. Fri: a.m./p.m. to a.m./p.m.
Tue: a.m./p.m. to a.m./p.m. Sat: a.m./p.m. to a.m./p.m.
Wed: a.m./p.m. to a.m./p.m. Sun: a.m./p.m. to a.m./p.m.
Thu: a.m./p.m. to a.m./p.m.
## Section III – Ownership Information

<table>
<thead>
<tr>
<th>TYPE OF OWNERSHIP</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Publicly Held Corporation</td>
</tr>
<tr>
<td>□ Partnership</td>
</tr>
</tbody>
</table>

List the state of incorporation or state of organization (except Partnership = General or Sole Proprietorship). Business entities organized under non-U.S. laws list the country of organization.

□ N/A (Partnership = General or Sole Proprietorship)

<table>
<thead>
<tr>
<th>State or Country:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

List the name, position/title, social security number, date of birth and address of each owner, partner, member, manager, officer, director, chief executive, or other person who directly or indirectly controls the operation of the business entity, as applicable. For example, corporations would list officers and directors, limited liability companies would list members and managers, etc.

<table>
<thead>
<tr>
<th>Name &amp; Title:</th>
<th>Social Security #:</th>
<th>Date of Birth:</th>
<th>% of Ownership:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
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<td>Date of Birth:</td>
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</tr>
</tbody>
</table>

DBPR-DDC-233 - Application for Permit as a Diethyl Ether Manufacturer, Distributor, Dealer, or Purchaser
Incorporated by rule(s): 61N-2.004, F.A.C.
Eff. Date: April 2016
Page 5 of 9
List the name, social security number, date of birth and address of each person who owns 10 percent or more of the outstanding stock or equity interest in the business entity.

<table>
<thead>
<tr>
<th>Name:</th>
<th>Social Security #:</th>
<th>Date of Birth:</th>
<th>% of Ownership:</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>
### Section IV – Background Questions

<table>
<thead>
<tr>
<th>Background Questions</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has the owner or any corporate officer been convicted of a felony under</td>
<td></td>
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<tr>
<td>the prescription drug or controlled substance laws of Florida or any other</td>
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<tr>
<td>state or federal jurisdiction, regardless of whether a pardon has been</td>
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<tr>
<td>granted or whether civil rights have been restored?</td>
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<tr>
<td>Has the owner or any corporate officer been convicted of a felony other</td>
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<tr>
<td>than a felony under the prescription drug or controlled substance laws of</td>
<td></td>
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</tr>
<tr>
<td>Florida or any other state or federal jurisdiction and not been granted a</td>
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<tr>
<td>pardon or had civil rights restored?</td>
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<tr>
<td>Has the owner or any corporate officer been adjudicated mentally</td>
<td></td>
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<tr>
<td>incompetent and not had civil rights restored?</td>
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</tr>
<tr>
<td>Has the owner or any corporate officer been denied a permit or license in</td>
<td></td>
<td></td>
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<tr>
<td>any state related to any activity regulated under Chapter 499, F.S.?</td>
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</tbody>
</table>

If you answered “YES” to any questions in Section IV, you must provide detailed explanations in Section V, including requirements for submitting supporting legal documents. If needed, explain on separate sheet(s).

### Section V – Explanation(s) for “Yes” response(s) to background question(s) in Section IV

<table>
<thead>
<tr>
<th>Explanation(s)</th>
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DBPR-DDC-233 - Application for Permit as a Diethyl Ether Manufacturer, Distributor, Dealer, or Purchaser
Incorporated by rule(s): 61N-2.004, F.A.C.
Eff. Date: April 2016
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Section VI – Affidavit

**AFFIDAVIT**

Pursuant to s. 559.79, F.S., each application for a license or renewal of a license issued by the Department of Business and Professional Regulation shall be signed under oath or affirmation by the applicant, or owner or chief executive of the applicant without the need for witnesses unless otherwise required by law.

Pursuant to s. 559.791, F.S., any license issued by the Department of Business and Professional Regulation which is issued or renewed in response to an application upon which the person signing under oath or affirmation has falsely sworn to a material statement, including, but not limited to, the names and addresses of the owners or managers of the licensee or applicant, shall be subject to denial of the application or suspension or revocation of the license, and the person falsely swearing shall be subject to any other penalties provided by law.

I UNDERSTAND THAT THE ISSUANCE OF A PERMIT BY THE DEPARTMENT ONLY AUTHORIZES THE APPLICANT TO CONDUCT REGULATED ACTIVITIES IN THE STATE OF FLORIDA UNDER THE NAME IN WHICH THE PERMIT IS ISSUED. IF THE PERMIT IS ISSUED IN THE NAME OF A DBA OR D/B/A THE APPLICANT MAY ONLY CONDUCT BUSINESS IN FLORIDA IN THE NAME OF THE DBA OR D/B/A.

I FURTHER UNDERSTAND THAT PROVIDING ADDITIONAL DBA OR D/B/A NAMES TO THE DEPARTMENT AS PART OF THE APPLICATION PROCESS IS NOT, UPON LICENSURE, AN AUTHORIZATION TO CONDUCT BUSINESS IN FLORIDA UNDER THE NAME OF THOSE ADDITIONAL DBA’S OR D/B/A’S.

I certify that I am empowered to execute this application as required by s. 559.79, F.S. I understand that my signature on this application has the same legal effect as if made under oath. To the best of my knowledge, all information contained on this application is true and correct. I understand the falsification of any information on this application may result in administrative action, including a fine, suspension, or revocation of the license.

Signature of Applicant, Owner or Chief Executive: __________________________ Date: ________________

Print Name: ________________________ Title: ________________________
Mail completed application to:

Department of Business and Professional Regulation
1940 North Monroe Street
Tallahassee, FL 32399
61N-2.005 Application for Freight Forwarder Permit

A freight forwarder permit is required for any person that engages in the distribution of a prescription drug as a freight forwarder unless the person is a common carrier. A person, prior to engaging in activity for which a freight forwarder permit is required, must file an application on form number DBPR-DDC-225, Application for Permit as a Freight Forwarder, effective April 2016, adopted and incorporated herein by reference and comply with all the requirements for permitting in Chapter 499, F.S. and Rule 61N, F.A.C. This form is available upon request from the Division of Drugs, Devices and Cosmetics at 1940 N. Monroe Street, Tallahassee, Florida 32399, (850) 717-1800, or at http://www.firules.org/Gateway/reference.asp?No=Ref-06906

Rulemaking Authority 499.012(3), 499.05 FS. Law Implemented 499.01, 499.012, 499.0121, 499.04, 499.041 FS. History-New-
State of Florida  
Department of Business and Professional Regulation  
Division of Drugs, Devices, and Cosmetics  

Application for Permit as a Freight Forwarder  
Form No.: DBPR-DDC-225

APPLICATION CHECKLIST – IMPORTANT – Submit all items on the checklist below with your application to ensure faster processing.

<table>
<thead>
<tr>
<th>APPLICATION</th>
<th>APPLICATION REQUIREMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application for Permit as a Freight Forwarder</td>
<td></td>
</tr>
</tbody>
</table>
- Enclose the fee of $750.00, which includes $600.00 biennial application fee and $150.00 initial application/on-site inspection fee.  
- Make cashier’s check, corporate or business check, or money order payable to the Florida Department of Business and Professional Regulation.  
- If the applicant answered “Yes” to any question in Section IV, enclose a detailed explanation along with any relevant documentation.  
- Sign and date the Affidavit section of the application.  
- Submit the completed application with enclosures to: Department of Business and Professional Regulation 1940 North Monroe Street Tallahassee, FL 32399 |

PLEASE NOTE:  
Telephone, email, and fax contact information is used to quickly resolve questions with applications. If such information is not provided, questions regarding applications will be mailed to the application contact's mailing address and may take longer to resolve.
Section I – Application Type

CHECK ONE OF THE APPLICATION TYPES

☐ New Application [3327/1020]
☐ New Application due to change in ownership. If checked, provide legal documentation for the change of ownership (i.e. Bill of Sale, stock transfer, merger). [3327/1020]

Current Permit Number:

Section II – Applicant Information

TAXPAYER IDENTIFICATION NUMBER OR FEDERAL EMPLOYER IDENTIFICATION NUMBER

This is a unique nine-digit number assigned by the Internal Revenue Service (IRS) to business entities operating in the United States for the purposes of identification. When the number is used for identification rather than employment tax reporting, it is usually referred to as a Taxpayer Identification Number (TIN), and when used for the purposes of reporting employment taxes, it is usually referred to as the Federal Employer Identification Number (FEIN).

Applicant’s TIN/FEIN:

FULL LEGAL NAME

The “full legal name” is the complete name of the business entity that will be operating the establishment. This is generally the name that is on the documents that establish the existence or formation of the business entity. For example, a corporation’s full legal name would normally be the name that is found in the corporation’s articles of incorporation.

Applicant’s Full Legal Name:

FICTITIOUS, TRADE, OR BUSINESS NAME

If the applicant intends to operate the permitted establishment under a name that is different from the Applicant’s Full Legal Name listed above – e.g. fictitious, trade, or business name (also commonly referred to as a “dba”, “D/B/A”, or “doing business as” name – this name must be registered with the Florida Department of State, Division of Corporations. This is the name that will appear on the permit issued to the applicant by the department and must be the name that the applicant uses on operational documents for permitted activities.

☐ The applicant WILL NOT operate the permitted establishment under a name that is different from the Applicant’s Full Legal Name listed above.

☐ The applicant WILL operate the permitted establishment under the following fictitious, trade, or business name:

The fictitious, trade, or business name listed directly above, is registered with the Florida Department of State, Division of Corporations and the applicant has been issued the following registration number:

APPLICANT’S MAILING ADDRESS

Street Address or P.O. Box:

City: ___________________________ State: ___________ Zip Code (+4 optional): ___________

PHYSICAL ADDRESS OF ESTABLISHMENT TO BE PERMITTED
(only if different from mailing address) Check [ ] if not applicable

Street Address:

City: ___________________________ State: ___________ Zip Code (+4 optional): ___________

County (if located in Florida): ___________ Country: ___________

E-Mail Address: ___________________________ Phone Number: ___________________________

APPLICATION CONTACT

The application contact is the person that the department will contact if there are questions regarding the responses provided on, or the documentation submitted with, the application. The application contact is also the person that will receive all official communication from the department regarding the application.

Last/Surname: ___________ First: ___________ Middle: ___________ Suffix: ___________

Address: ___________________________

City: ___________________________ State: ___________ Zip Code (+4 optional): ___________

Telephone Number: ___________________________ Fax Number: ___________________________

E-Mail Address: ___________________________

EMERGENCY CONTACT – RESIDENT INFORMATION

The emergency contact is the person that the department will contact in the case of an emergency. During an emergency, the department will contact this person at times outside of the regular business hours listed below. The contact information provided should be sufficient for the department to actually reach and communicate with the person listed in the event of an emergency.

Last/Surname: ___________ First: ___________ Middle: ___________ Suffix: ___________

Position/Title: ___________________________

Street Address: ___________________________

City: ___________________________ State: ___________ Zip Code (+4 optional): ___________

Telephone Number: ___________________________ E-Mail Address: ___________________________
OPERATING HOURS
List the establishment's daily hours of operation in terms of Eastern Time. REMEMBER to circle “a.m.” or “p.m.” for each time indicated below.

<table>
<thead>
<tr>
<th>Day</th>
<th>a.m./p.m. to a.m./p.m.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mon</td>
<td></td>
</tr>
<tr>
<td>Tue</td>
<td></td>
</tr>
<tr>
<td>Wed</td>
<td></td>
</tr>
<tr>
<td>Thu</td>
<td></td>
</tr>
<tr>
<td>Fri</td>
<td>a.m./p.m. to a.m./p.m.</td>
</tr>
<tr>
<td>Sat</td>
<td>a.m./p.m. to a.m./p.m.</td>
</tr>
<tr>
<td>Sun</td>
<td>a.m./p.m. to a.m./p.m.</td>
</tr>
</tbody>
</table>

Section III – Ownership Information

TYPE OF OWNERSHIP

- Publicly Held Corporation
- Closely Held Corporation
- Limited Liability Company
- Charitable Organization—501(c)(3)
- Sole Proprietorship
- Government
- Partnership – General
- Professional Corporation or Association
- Professional Limited Liability Company
- Partnership – Other, Including Limited Liability Partnership
- Other: _______________________

List the state of incorporation or state of organization (except Partnership – General or Sole Proprietorship). Business entities organized under non-U.S. laws list the country of organization.

- N/A (Partnership – General or Sole Proprietorship)

State or Country:

List name and address of the applicant’s registered agent for service of process in Florida (except Sole Proprietorship or Partnership – General) and provide documentation, such as a print out from the Florida Department of State, Division of Corporations’ webpage, that the applicant’s registered agent is registered with the Florida Department of State, Division of Corporations.

- N/A (Partnership – General or Sole Proprietorship)

Name:

Address:

City: State: Zip Code (+4 Optional):

List the name, position/title, social security number, date of birth and address of each owner, partner, member, manager, officer, director, chief executive, or other person who directly or indirectly controls the operation of the business entity, as applicable. For example, corporations would list officers and directors, limited liability companies would list members and managers, etc.

1. Name & Title: Social Security #: Date of Birth: % of Ownership:
   Street Address: City: State: Zip Code:

2. Name & Title: Social Security #: Date of Birth: % of Ownership:
<table>
<thead>
<tr>
<th>Street Address:</th>
<th>City:</th>
<th>State:</th>
<th>Zip Code:</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Name &amp; Title:</td>
<td>Social Security #:</td>
<td>Date of Birth:</td>
<td>% of Ownership:</td>
</tr>
<tr>
<td>Street Address:</td>
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<tr>
<td>4. Name &amp; Title:</td>
<td>Social Security #:</td>
<td>Date of Birth:</td>
<td>% of Ownership:</td>
</tr>
<tr>
<td>Street Address:</td>
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<td>State:</td>
<td>Zip Code:</td>
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<tr>
<td>5. Name &amp; Title:</td>
<td>Social Security #:</td>
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<td>% of Ownership:</td>
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<td>Street Address:</td>
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<td>6. Name &amp; Title:</td>
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<td>7. Name &amp; Title:</td>
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<td>Street Address:</td>
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<td>8. Name &amp; Title:</td>
<td>Social Security #:</td>
<td>Date of Birth:</td>
<td>% of Ownership:</td>
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<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
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</tbody>
</table>

List the name, social security number, date of birth and address of each person who owns 10 percent or more of the outstanding stock or equity interest in the business entity:

<table>
<thead>
<tr>
<th>1. Name:</th>
<th>Social Security #:</th>
<th>Date of Birth:</th>
<th>% of Ownership:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Name:</th>
<th>Social Security #:</th>
<th>Date of Birth:</th>
<th>% of Ownership:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street Address:</td>
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</tbody>
</table>

DBPR-DDC-225- Application for Permit as a Freight Forwarder
Incorporated by rule: 61N-2.005, F.A.C.
Eff. Date: April 2016
Page 5 of 11
<table>
<thead>
<tr>
<th></th>
<th>Name:</th>
<th>Social Security #:</th>
<th>Date of Birth:</th>
<th>% of Ownership:</th>
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</thead>
<tbody>
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<td>6.</td>
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</table>

List all trade or business names used by the applicant. Use additional sheet(s) if necessary. If the applicant does not use other trade or business names check this box [ ] and write N/A on the lines below.

<table>
<thead>
<tr>
<th></th>
<th>Parent Company Name</th>
<th>% of Ownership</th>
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<tbody>
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</table>

Is the applicant a subsidiary of another company? (If yes, provide a listing of all parent companies with percentages of ownership, using additional sheet(s) if necessary). Note: A permit issued pursuant to this application is only valid for the applicant, and the applicant's name and address. (If no, please check this box [ ] and write "N/A" in the lines below).

□ Yes  □ No
### BACKGROUND QUESTIONS

<p>| | | | |</p>
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<tbody>
<tr>
<td>1.</td>
<td>□ Yes</td>
<td>□ No</td>
<td>Has the applicant or any &quot;affiliated party&quot; (defined below) been found guilty of (regardless of adjudication), or pled no contest to, in any jurisdiction, a violation of law that directly relates to a drug, device, or cosmetic?</td>
</tr>
<tr>
<td>2.</td>
<td>□ Yes</td>
<td>□ No</td>
<td>Has the applicant or any affiliated party (defined below) been fined or disciplined by a regulatory agency in any state (including Florida) for any offense that would constitute a violation of Chapter 499, F.S.?</td>
</tr>
<tr>
<td>3.</td>
<td>□ Yes</td>
<td>□ No</td>
<td>Has the applicant or any affiliated party (defined below) been convicted (regardless of adjudication) of any felony under a federal, state (including Florida), or local law?</td>
</tr>
<tr>
<td>4.</td>
<td>□ Yes</td>
<td>□ No</td>
<td>Has the applicant or any affiliated party (defined below) been denied a permit or license in any state (including Florida) related to an activity regulated under Chapters 456, 465, 499, or 893, F.S.?</td>
</tr>
<tr>
<td>5.</td>
<td>□ Yes</td>
<td>□ No</td>
<td>Has the applicant or any affiliated party (defined below) had any current or previous permit or license suspended or revoked which was issued by a federal, state, or local governmental agency relating to the manufacture or distribution of drugs, devices, or cosmetics?</td>
</tr>
<tr>
<td>6.</td>
<td>□ Yes</td>
<td>□ No</td>
<td>Has the applicant or any affiliated party (defined below) ever held a permit issued under Chapter 499, F.S., in a different name than the applicant's name? (If yes, provide the names in which each permit was issued and at what address).</td>
</tr>
</tbody>
</table>

The term "affiliated party" means: (a) a director, officer, trustee, partner, or committee member of a permittee or applicant or a subsidiary or service corporation of the permittee or applicant; (b) a person who, directly or indirectly, manages, controls, or oversees the operation of a permittee or applicant, regardless of whether such person is a partner, shareholder, manager, member, officer, director, independent contractor, or employee of the permittee or applicant; (c) a person who has filed or is required to file a personal information statement pursuant to s. 499.012(8) or is required to be identified in an application for a permit or to renew a permit pursuant to s. 499.012(8); or (d) the five largest natural shareholders that own at least 5 percent of the permittee or applicant.

If you answered "YES" to any questions in Section IV, you must provide detailed explanations in Section V, including requirements for submitting supporting legal documents. If needed, explain on separate sheet(s).

### Section V – Explanation(s) for “Yes” response(s) to background question(s) in Section IV

<table>
<thead>
<tr>
<th>EXPLANATION(S)</th>
</tr>
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</table>
Section VI – Other Permits or Licenses

PERMITS OR LICENSES

1. Are there any other permits or licenses issued by any agency of the State of Florida that authorize the purchase or possession of prescription drugs at the applicant’s establishment or address? (If yes, provide the name in which the permit is issued, the permit type, and permit number in the spaces provided below). (If no, please check this box ☐ and write "N/A" in the lines below).

☐ Yes  ☐ No

1a. Permit/License Name  Permit/License Type  Permit/License Number

Section VII – Freight Forwarding Activity

DISTRIBUTION ACTIVITIES

Generally identify the applicant’s intended customers (i.e. the types of owners / establishments for whom / which the applicant will be receiving prescription drugs designated for export and subsequently exporting those prescription drugs).

☐ Manufacturers  ☐ Wholesalers  ☐ Pharmacies
☐ Hospitals  ☐ Practitioners  ☐ Clinics
☐ Veterinarians
Identify the types of products the applicant will engage in the receipt and distribution (exporting) of under this permit. Check all that apply.

<table>
<thead>
<tr>
<th>Human Prescription Drugs</th>
<th>Veterinary Prescription Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Solid Dose</td>
<td>☐ Refrigerated (Human, Veterinary, or Otherwise)</td>
</tr>
<tr>
<td>☐ Liquids (Oral)</td>
<td>☐ Frozen (Human, Veterinary, or Otherwise)</td>
</tr>
<tr>
<td>☐ Injectables</td>
<td></td>
</tr>
<tr>
<td>☐ Topical</td>
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<tr>
<td>☐ Dental</td>
<td></td>
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<tr>
<td>☐ Ophthalmic</td>
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<tr>
<td>☐ Compressed Medical Gases</td>
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</tbody>
</table>

Controlled Substances: Provide your DEA Number: ____________ or check ☐ No DEA Number

Check Schedules: ☐ Sch II ☐ Sch III ☐ Sch IV ☐ Sch V

1. Are products to be distributed under this permit intended for export? If not, then a permit as a prescription drug wholesaler may be required. ☐ Yes ☐ No

2. Will all required records be stored and maintained at applicant’s physical address? (If no, provide the address of the establishments where all required records will be stored and maintained under question #3.) ☐ Yes ☐ No

3. Physical address where required records will be stored

   Street Address:

   City: ___________________________  State: _______________________  Zip Code (+4 optional): ____________

4. Will the required records be computerized, automated or stored electronically? If yes, will you have a back-up procedure to be able to provide required records? ☐ Yes ☐ No

5. Is the applicant’s establishment equipped with an alarm system to detect entry after hours and a security system protecting against theft and diversion?

   (If yes, provide a written description of the alarm and security systems, that include: the type of system and how the system is monitored)

   Description included? ☐ Yes ☐ No ☐ N/A

   (If no, provide a written explanation of why the establishment is not equipped with an alarm or security system.)

   Explanation included? ☐ Yes ☐ No ☐ N/A

6. Is there a quarantine area at the applicant’s establishment for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened?

   If no, provide a written explanation of why the establishment does not have a quarantine area.

   Explanation included? ☐ Yes ☐ No ☐ N/A

7. Is the applicant’s establishment equipped with adequate climate controls (including refrigerated and freezing storage if appropriate for the applicant’s distributed products) to ensure safe storage? ☐ Yes ☐ No
8. Do you understand that you must maintain a validated airway bill, bill of lading, or other appropriate documentation to evidence the exportation of prescription drugs? □ Yes □ No

9. Provide the names and addresses of all persons for which you have an ongoing relationship to receive prescription drugs for exportation. (If none check □ and write "N/A" in the lines below)

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10. Do you understand that if you purchase prescription drugs, or take title or ownership of prescription drugs, that you must also obtain a prescription drug wholesale distributor permit? □ Yes □ No

11. Do you understand that prescription drugs that you receive for export as a freight forwarder cannot be sent anywhere or distributed to any location in the United States other than to another permitted freight forwarder for export? □ Yes □ No

12. Does the applicant have written policies and procedures to include: the receipt, security, storage, inventory, distribution/disposition of prescription drugs; distributing oldest approved stock first (FIFO); identifying, recording and reporting prescription drug losses and thefts; maintenance, retrieval and retention of required records; prescription drug recalls and withdrawals; natural disasters and other emergencies; segregation and destruction of outdated products; and temperature and humidity monitoring?

   (If no, provide written explanation for lack of specific policy or procedure identified above).

   Explanation attached? □ Yes □ No □ N/A

   (If yes, provide a copy of each policy and procedure. Label each policy and procedure specifically identifying the subject matter in the list above that is covered by the policy or procedure. For example, the policy or procedure for receipt, security, storage, inventory could be labeled or identified as "Policy and/or Procedure for receipt, security, storage, inventory" or in another manner similar to this example.

   Policies attached? □ Yes □ No □ N/A
   Policies labeled? □ Yes □ No □ N/A

13. Provide the date the establishment will be ready and available for inspection. This is the earliest date the application may be deemed complete. □/□/□□
Pursuant to s. 559.79, F.S., each application for a license or renewal of a license issued by the Department of Business and Professional Regulation shall be signed under oath or affirmation by the applicant, or owner or chief executive of the applicant without the need for witnesses unless otherwise required by law.

Pursuant to s. 559.791, F.S., any license issued by the Department of Business and Professional Regulation which is issued or renewed in response to an application upon which the person signing under oath or affirmation has falsely sworn to a material statement, including, but not limited to, the names and addresses of the owners or managers of the licensee or applicant, shall be subject to denial of the application or suspension or revocation of the license, and the person falsely swearing shall be subject to any other penalties provided by law.

I UNDERSTAND THAT THE ISSUANCE OF A PERMIT BY THE DEPARTMENT ONLY AUTHORIZES THE APPLICANT TO CONDUCT REGULATED ACTIVITIES IN THE STATE OF FLORIDA UNDER THE NAME IN WHICH THE PERMIT IS ISSUED. IF THE PERMIT IS ISSUED IN THE NAME OF A DBA OR D/B/A THE APPLICANT MAY ONLY CONDUCT BUSINESS IN FLORIDA IN THE NAME OF THE DBA OR D/B/A.

I FURTHER UNDERSTAND THAT PROVIDING ADDITIONAL DBA OR D/B/A NAMES TO THE DEPARTMENT AS PART OF THE APPLICATION PROCESS IS NOT, UPON LICENSURE, AN AUTHORIZATION TO CONDUCT BUSINESS IN FLORIDA UNDER THE NAME OF THOSE ADDITIONAL DBA’S OR D/B/A’S.

I certify that I am empowered to execute this application as required by s. 559.79, F.S. I understand that my signature on this application has the same legal effect as if made under oath. To the best of my knowledge, all information contained on this application is true and correct. I understand the falsification of any information on this application may result in administrative action, including a fine, suspension, or revocation of the license.

Signature of Applicant, Owner or Chief Executive: Date:

Print Name: Title:

Mail completed application to:

Department of Business and Professional Regulation
1940 North Monroe Street
Tallahassee, FL 32399
A health care clinic establishment permit is required for the purchase of a prescription drug by a place of business at one general physical location that provides health care or veterinary services, which is owned and operated by a business entity that has been issued a federal employer tax identification number. A person located in this state, prior to engaging in activity for which a health care clinic establishment permit is required, must file a completed application on form number DBPR-DDC-224, Application for Permit as a Health Care Clinic Establishment, effective April 2016, adopted and incorporated herein by reference and comply with all the requirements for permitting in Chapter 499, F.S. and Rule 61N, F.A.C. This form is available upon request from the Division of Drugs, Devices and Cosmetics at 1940 N. Monroe Street, Tallahassee, Florida 32399, (850)717-1800, or at http://www.flrules.org/Gateway/reference.asp?No=Ref-06908

Rulemaking Authority 499.012(3), 499.05 FS. Law Implemented 499.01, 499.012, 499.0121, 499.04, 499.041 FS. History-New-
APPLICATION CHECKLIST – IMPORTANT – Submit all items on the checklist below with your application to ensure faster processing.

<table>
<thead>
<tr>
<th>APPLICATION</th>
<th>APPLICATION REQUIREMENTS</th>
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<tbody>
<tr>
<td>Application for Permit as a Health</td>
<td>Submit a biennial application fee of $255.00, made payable by cashier’s check, corporate or business check, or money order, to the Florida</td>
</tr>
<tr>
<td>Care Clinic Establishment</td>
<td>Department of Business and Professional Regulation.</td>
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<td>If you answer “Yes” to any question in Section IV, be sure to provide a detailed explanation along with any relevant documentation.</td>
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<tr>
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<td>Sign and date the Affidavit section of the application.</td>
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<tr>
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<td>Submit the completed application with enclosures to:</td>
</tr>
<tr>
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<td>Department of Business and Professional Regulation</td>
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<td></td>
<td>1940 North Monroe Street</td>
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<td></td>
<td>Tallahassee, FL 32399</td>
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</tbody>
</table>

PLEASE NOTE:
Telephone, email, and fax contact information is used to quickly resolve questions with applications. If such information is not provided, questions regarding applications will be mailed to the application contact’s mailing address and may take longer to resolve.
Application for Permit as a Health Care Clinic Establishment
Form No.: DBPR-DDC-224

If you have any questions or need assistance in completing this application, please contact the
Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics, at
850.717.1800. For additional information see the instructions at the beginning of this application.

Section I – Application Type

CHECK ONE OF THE APPLICATION TYPES

☐ New Application [3360/1020]
☐ New Application due to Change in Ownership. If checked, provide legal documentation for the
change of ownership (i.e. Bill of Sale, stock transfer, merger). [3360/1020]
  Current Permit Number: __________________________

Section II – Applicant Information

APPLICANT INFORMATION

TAXPAYER IDENTIFICATION NUMBER OR FEDERAL EMPLOYER IDENTIFICATION NUMBER
This is a unique nine-digit number assigned by the Internal Revenue Service (IRS) to business entities
operating in the United States for the purposes of identification. When the number is used for
identification rather than employment tax reporting, it is usually referred to as a Taxpayer Identification
Number (TIN), and when used for the purposes of reporting employment taxes, it is usually referred to as
the Federal Employer Identification Number (FEIN).
Applicant’s TIN/FEIN:

FULL LEGAL NAME
The “full legal name” is the complete name of the business entity that will be operating the establishment.
This is generally the name that is on the documents that establish the existence or formation of the
business entity. For example, a corporation’s full legal name would normally be the name that is found in
the corporation’s articles of incorporation.
Applicant’s Full Legal Name:

FICTIONOUS, TRADE, OR BUSINESS NAME
If the applicant intends to operate the permitted establishment under a name that is different from the
Applicant’s Full Legal Name listed above – e.g. fictitious, trade, or business name (also commonly
referred to as a “dba”, “D/B/A”, or “doing business as” name – this name must be registered with the
Florida Department of State, Division of Corporations. This is the name that will appear on the permit
issued to the applicant by the department and must be the name that the applicant uses on operational
documents for permitted activities.

☐ The applicant WILL NOT operate the permitted establishment under a name that is different from the
  Applicant’s Full Legal Name listed above.

☐ The applicant WILL operate the permitted establishment under the following fictitious, trade, or
  business name:

  The fictitious, trade, or business name listed directly above, is registered with the Florida Department
  of State, Division of Corporations and the applicant has been issued the following registration
  number:

  __________________________
### Applicant's Mailing Address

<table>
<thead>
<tr>
<th>Street Address or P.O. Box:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<table>
<thead>
<tr>
<th>City:</th>
<th>State:</th>
<th>Zip Code (+4 optional):</th>
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</table>

### Physical Address of Establishment to Be Permitted

(only if different from mailing address) Check □ if not applicable

<table>
<thead>
<tr>
<th>Street Address:</th>
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</table>

<table>
<thead>
<tr>
<th>City:</th>
<th>State:</th>
<th>Zip Code (+4 optional):</th>
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<table>
<thead>
<tr>
<th>County (if Florida address):</th>
<th>Country:</th>
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<thead>
<tr>
<th>E-Mail Address:</th>
<th>Phone Number:</th>
<th>Fax Number:</th>
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</table>

### Application Contact

The application contact is the person that the department will contact if there are questions regarding the responses provided on, or the documentation submitted with, the application. The application contact is also the person that will receive all official communication from the department regarding the application.

<table>
<thead>
<tr>
<th>Last/Surname:</th>
<th>First:</th>
<th>Middle:</th>
<th>Suffix:</th>
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<th>Address:</th>
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<tr>
<th>City:</th>
<th>State:</th>
<th>Zip Code (+4 optional):</th>
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<thead>
<tr>
<th>Telephone Number:</th>
<th>Fax Number:</th>
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<table>
<thead>
<tr>
<th>E-Mail Address:</th>
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### Designated Qualifying Practitioner

The designated qualifying practitioner is the person that the department will contact regarding legal and or regulatory issues related to the purchase, recordkeeping, storage, and handling of prescription drugs. The department will contact this person at times outside of the regular business hours listed below. The contact information provided should be sufficient for the department to actually reach and communicate with the designated qualifying practitioner.

<table>
<thead>
<tr>
<th>Last/Surname:</th>
<th>First:</th>
<th>Middle:</th>
<th>Suffix:</th>
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<tr>
<th>Street Address:</th>
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<th>City:</th>
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<tr>
<th>Telephone Number:</th>
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License # With Prefix: Expiration Date: Issuing regulatory board (e.g.: Florida Board of Medicine):  

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</table>

Is qualified practitioner authorized under the appropriate practice act to prescribe and administer prescription drugs? If no, please explain.

□ Yes □ No □ N/A

Explanation Attached? □ Yes □ No □ N/A
Qualifying Practitioner Affidavit:

I UNDERSTAND that as the qualifying practitioner I will be responsible for complying with all legal and regulatory requirements related to the purchase, recordkeeping, storage, and handling of the prescription drugs.

I UNDERSTAND that my name, the establishment address, and my license number will be used on all distribution documents for prescription drugs purchased or returned by the health care clinic establishment.

I UNDERSTAND that a violation of Chapter 499, Florida Statutes, by the health care clinic establishment or me as the qualifying practitioner constitutes grounds for discipline of my health care practitioner license by the appropriate regulatory board.

Signature of Designated Qualifying Practitioner: ____________________________ Date: ______________________

OPERATING HOURS

List the establishment’s daily hours of operation in terms of Eastern Time. REMEMBER to circle “a.m.” or “p.m.” for each time indicated below.

<table>
<thead>
<tr>
<th>Day</th>
<th>a.m./p.m. to</th>
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<tbody>
<tr>
<td>Mon</td>
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Section III – Ownership Information

TYPE OF OWNERSHIP

- [ ] Publicly Held Corporation
- [ ] Closely Held Corporation
- [ ] Limited Liability Company
- [ ] Charitable Organization—501(c)(3)
- [ ] Sole Proprietorship
- [ ] Government
- [ ] Partnership – General
- [ ] Professional Corporation or Association
- [ ] Professional Limited Liability Company
- [ ] Partnership – Other, Including Limited Liability Partnership and Limited Partnership
- [ ] Other: ____________

List the state of incorporation or state of organization (except Partnership – General or Sole Proprietorship). Business entities organized under non-U.S. laws list the country of organization.

- [ ] N/A (Partnership – General or Sole Proprietorship)

State or Country: ____________________________
List the name, address of the applicant's registered agent for service of process in Florida (except Sole Proprietorship or Partnership - General) and provide documentation, such as a print out from the Florida Department of State, Division of Corporations' webpage, that the applicant's registered agent is registered with the Florida Department of State, Division of Corporations.

Name:
Address:
City:  State:  Zip Code (+4 optional):

List the name, position/title, social security number, date of birth and address of each owner, partner, member, manager, officer, director, chief executive, or other person who directly or indirectly controls the operation of the business entity, as applicable. For example, corporations would list officers and directors. Limited liability companies would list members and managers, etc.

1. Name & Title: [ ]  Social Security #: [ ]  Date of Birth: [ ]  % of Ownership: [ ]
   Street Address: [ ]  City: [ ]  State: [ ]  Zip Code: [ ]

2. Name & Title: [ ]  Social Security #: [ ]  Date of Birth: [ ]  % of Ownership: [ ]
   Street Address: [ ]  City: [ ]  State: [ ]  Zip Code: [ ]

3. Name & Title: [ ]  Social Security #: [ ]  Date of Birth: [ ]  % of Ownership: [ ]
   Street Address: [ ]  City: [ ]  State: [ ]  Zip Code: [ ]

4. Name & Title: [ ]  Social Security #: [ ]  Date of Birth: [ ]  % of Ownership: [ ]
   Street Address: [ ]  City: [ ]  State: [ ]  Zip Code: [ ]

5. Name & Title: [ ]  Social Security #: [ ]  Date of Birth: [ ]  % of Ownership: [ ]
   Street Address: [ ]  City: [ ]  State: [ ]  Zip Code: [ ]

List the name, social security number, date of birth and address of each person who owns 10 percent or more of the outstanding stock or equity interest in the business entity.

1. Name: [ ]  Social Security #: [ ]  Date of Birth: [ ]  % of Ownership: [ ]
   Street Address: [ ]  City: [ ]  State: [ ]  Zip Code: [ ]
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<th></th>
<th>Name:</th>
<th>Social Security #:</th>
<th>Date of Birth:</th>
<th>% of Ownership:</th>
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List all trade or business names used by the applicant. Use additional sheet(s) if necessary. If the applicant does not use other trade or business names check this box □ and write N/A on the lines below.

## Section IV – Background Questions

**BACKGROUND QUESTIONS**

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
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<tbody>
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<td>1.</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
If yes, explain in detail in Section V

Has the applicant or designated qualifying practitioner been fined or disciplined by a regulatory agency in any state (Including Florida) for any offense that would constitute a violation of Chapters 456, 465, 474, 499, or 893, F.S., related to the distribution, possession, administration, or dispensing of prescription drugs?

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
If yes, explain in detail in Section V

Has the applicant or designated qualifying practitioner ever entered a plea to, been convicted or found guilty of, any felony under a federal, state (including Florida), or local law related to the distribution, possession, administration or dispensing of prescription drugs? Include all cases where a guilty, nolo contendere or no contest plea was entered, whether or not adjudication was withheld.

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
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<td>3.</td>
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<td></td>
<td>Yes</td>
<td>No</td>
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</tbody>
</table>
If yes, explain in detail in Section V

Has the applicant or designated qualifying practitioner had any current or previous permit or license suspended or revoked which was issued by a federal, state, or local government agency relating to the manufacturing, distributing, prescribing, dispensing, or administration of prescription drugs?

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
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<tbody>
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<td>4.</td>
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<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
If yes, explain in detail in Section V

Has the applicant or designated qualifying practitioner been denied a permit or license in any state (including Florida) related to an activity regulated under Chapters 465, 499, or 893, F.S.?
If you answered “YES” to any questions in Section IV, you must provide detailed explanations in Section V, including requirements for submitting supporting legal documents. If needed, explain on separate sheet(s).

**Section V – Explanation(s) for “Yes” response(s) to background question(s) in Section IV**

<table>
<thead>
<tr>
<th>EXPLANATION(S)</th>
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</table>

**Section VI – Other Permits or Licenses**

<table>
<thead>
<tr>
<th>PERMITS OR LICENSES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Are there any other permits or licenses issued by any agency of the State of Florida that authorize the purchase or possession of prescription drugs at the applicant’s establishment or address? (If no, please check this box [ ] and write “N/A” in the lines below).</td>
</tr>
<tr>
<td>□ Yes □ No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Permit/License Name</th>
<th>Permit/License Type</th>
<th>Permit/License Number</th>
</tr>
</thead>
<tbody>
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DBPR-DDC-224 - Application for Permit as a Health Care Clinic Establishment
Incorporated by rule: 61N-2.006, F.A.C.
Eff. Date: April 2016
Page 7 of 8
Pursuant to s. 559.79, F.S., each application for a license or renewal of a license issued by the Department of Business and Professional Regulation shall be signed under oath or affirmation by the applicant, or owner or chief executive of the applicant without the need for witnesses unless otherwise required by law.

Pursuant to s. 559.791, F.S., any license issued by the Department of Business and Professional Regulation which is issued or renewed in response to an application upon which the person signing under oath or affirmation has falsely sworn to a material statement, including, but not limited to, the names and addresses of the owners or managers of the licensee or applicant, shall be subject to denial of the application or suspension or revocation of the license, and the person falsely swearing shall be subject to any other penalties provided by law.

I UNDERSTAND THAT THE ISSUANCE OF A PERMIT BY THE DEPARTMENT ONLY AUTHORIZES THE APPLICANT TO CONDUCT REGULATED ACTIVITIES IN THE STATE OF FLORIDA UNDER THE NAME IN WHICH THE PERMIT IS ISSUED. IF THE PERMIT IS ISSUED IN THE NAME OF A DBA OR D/B/A, THE APPLICANT MAY ONLY CONDUCT BUSINESS IN FLORIDA IN THE NAME OF THE DBA OR D/B/A.

I FURTHER UNDERSTAND THAT PROVIDING ADDITIONAL DBA OR D/B/A NAMES TO THE DEPARTMENT AS PART OF THE APPLICATION PROCESS IS NOT, UPON LICENSURE, AN AUTHORIZATION TO CONDUCT BUSINESS IN FLORIDA UNDER THE NAME OF THOSE ADDITIONAL DBA’S OR D/B/A’S.

I certify that I am empowered to execute this application as required by s. 559.79, F.S. I understand that my signature on this application has the same legal effect as if made under oath. To the best of my knowledge, all information contained on this application is true and correct. I understand the falsification of any information on this application may result in administrative action, including a fine, suspension, or revocation of the license.

Signature of Applicant, Owner or Chief Executive:  
Date:  
Print Name:  
Title:

Mail completed application to:
Department of Business and Professional Regulation
1940 North Monroe Street
Tallahassee, FL 32399
61N-2.008 Application for Medical Gas Manufacturer Permit

A medical gas manufacturer permit is required for a person or entity located in this state which engages in the manufacture of medical gases by physical air separation, chemical action, purification, or filling containers by a liquid-to-liquid, liquid-to-gas, or gas-to-gas process and distributes those medical gases within this state. A person located in this state, prior to engaging in activity for which a medical gas manufacturer permit is required, must file with the department a completed application on form number DBPR-DDC-204, Application for Permit as a Medical Gas Manufacturer, effective April 2016, adopted and incorporated herein by reference and comply with all the requirements for permitting in Chapter 499, F.S. and Rule 61N, F.A.C. This form is available upon request from the Division of Drugs, Devices and Cosmetics at 1940 N. Monroe Street, Tallahassee, Florida 32399, (850) 717-1800, or at http://www.flrules.org/Gateway/reference.asp?No=Ref-06909

Rulemaking Authority 499.831, 499.832, 499.834 FS. Law Implemented 499.81, 499.83, 499.831, 499.833, 499.834, 499.84, 499.85, 499.86, 499.87, 499.88, 499.89, 499.90, 499.91, 499.92, 499.93, 499.931, 499.94 FS. History--New
APPLICATION CHECKLIST – IMPORTANT – Submit all items on the checklist below with your application to ensure faster processing.

<table>
<thead>
<tr>
<th>APPLICATION REQUIREMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submit fee of $1,150.00, which includes $1,000.00 biennial application fee and $150.00 initial application/on-site inspection fee. If the applicant is entitled to an exemption from inspection, the applicant would submit a fee of $1,000.00. If establishment is applying for multiple manufacturing permits in the applicant's name and at applicant's address, you are only required to pay for the permit with the highest fee.</td>
</tr>
<tr>
<td>Make cashier's check, corporate or business check, or money order payable to the Florida Department of Business and Professional Regulation.</td>
</tr>
<tr>
<td>If you answer &quot;Yes&quot; to any question in Section IV, be sure to provide a detailed explanation along with any relevant documentation.</td>
</tr>
<tr>
<td>If you take possession of medical gases at your establishment, provide a photocopy of the establishment's current fire inspection report.</td>
</tr>
<tr>
<td>The label you provide must include the statement required by rule 61N-1.007(3)(a) or (b). For example, if the container is non-disposable and may be refilled, the label must bear the statement &quot;federal law requires that this container be refilled with oxygen U.S.P. only by establishment registered as a drug producer in accordance with the Federal Food, Drug and Cosmetic Act.&quot; See rule 61N-1.007(3)(b), Florida Administrative Code.</td>
</tr>
<tr>
<td>Sign and date the Affidavit section of the application.</td>
</tr>
</tbody>
</table>

Submit the completed application with enclosures to:
Department of Business and Professional Regulation
1940 North Monroe Street
Tallahassee, FL 32399

PLEASE NOTE:
Telephone, email, and fax contact information is used to quickly resolve questions with applications. If such information is not provided, questions regarding applications will be mailed to the application contact's mailing address and may take longer to resolve.
Section I – Application Type

CHECK ONE OF THE APPLICATION TYPES

☐ New Application [3330/1020]

☐ New Application due to change in ownership. If checked, provide legal documentation for the change of ownership (i.e. Bill of Sale, stock transfer, merger). [3330/1020]

Current Permit Number: ______________________

Section II – Applicant Information

APPLICANT INFORMATION

TAXPAYER IDENTIFICATION NUMBER OR FEDERAL EMPLOYER IDENTIFICATION NUMBER

This is a unique nine-digit number assigned by the Internal Revenue Service (IRS) to business entities operating in the United States for the purposes of identification. When the number is used for identification rather than employment tax reporting, it is usually referred to as a Taxpayer Identification Number (TIN), and when used for the purposes of reporting employment taxes, it is usually referred to as the Federal Employer Identification Number (FEIN).

Applicant’s TIN/FEIN:

FULL LEGAL NAME

The "full legal name" is the complete name of the business entity that will be operating the establishment. This is generally the name that is on the documents that establish the existence or formation of the business entity. For example, a corporation’s full legal name would normally be the name that is found in the corporation’s articles of incorporation.

Applicant’s Full Legal Name:

FICTIONAL, TRADE, OR BUSINESS NAME

If the applicant intends to operate the permitted establishment under a name that is different from the Applicant’s Full Legal Name listed above – e.g. fictitious, trade, or business name (also commonly referred to as a “dba”, “D/B/A”, or "doing business as" name – this name must be registered with the Florida Department of State, Division of Corporations. This is the name that will appear on the permit issued to the applicant by the department and must be the name that the applicant uses on operational documents for permitted activities.

☐ The applicant WILL NOT operate the permitted establishment under a name that is different from the Applicant’s Full Legal Name listed above.

☐ The applicant WILL operate the permitted establishment under the following fictitious, trade, or business name:

________________________________________

The fictitious, trade, or business name listed directly above, is registered with the Florida Department of State, Division of Corporations and the applicant has been issued the following registration number:

________________________________________
APPLICANT'S MAILING ADDRESS

<table>
<thead>
<tr>
<th>Field</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street Address or P.O. Box:</td>
</tr>
<tr>
<td>City:</td>
</tr>
</tbody>
</table>

PHYSICAL ADDRESS OF ESTABLISHMENT TO BE PERMITTED
(only if different from mailing address) Check ☐ if not applicable

<table>
<thead>
<tr>
<th>Field</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street Address:</td>
</tr>
<tr>
<td>City:</td>
</tr>
<tr>
<td>County (if located in Florida):</td>
</tr>
<tr>
<td>E-Mail Address:</td>
</tr>
</tbody>
</table>

APPLICATION CONTACT

The application contact is the person that the department will contact if there are questions regarding the responses provided on, or the documentation submitted with, the application. The application contact is also the person that will receive all official communication from the department regarding the application.

<table>
<thead>
<tr>
<th>Field</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last/Surname:</td>
</tr>
<tr>
<td>Address:</td>
</tr>
<tr>
<td>City:</td>
</tr>
<tr>
<td>Telephone Number:</td>
</tr>
<tr>
<td>E-Mail Address:</td>
</tr>
</tbody>
</table>

EMERGENCY CONTACT

The emergency contact is the person that the department will contact in the case of an emergency. During an emergency, the department will contact this person at times outside of the regular business hours listed below. The contact information provided should be sufficient for the department to actually reach and communicate with the person listed in the event of an emergency.

<table>
<thead>
<tr>
<th>Field</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last/Surname:</td>
</tr>
<tr>
<td>Position/Title:</td>
</tr>
<tr>
<td>Street Address:</td>
</tr>
<tr>
<td>City:</td>
</tr>
<tr>
<td>Phone Number:</td>
</tr>
</tbody>
</table>
### Operating Hours

List the establishment’s daily hours of operation in terms of Eastern Time. REMEMBER to circle “a.m.” or “p.m.” for each time indicated below.

<table>
<thead>
<tr>
<th>Day</th>
<th>A.M./P.M. to</th>
<th>A.M./P.M. to</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mon</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tue</td>
<td></td>
<td></td>
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<tr>
<td>Wed</td>
<td></td>
<td></td>
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<tr>
<td>Thu</td>
<td></td>
<td></td>
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<tr>
<td>Fri</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sun</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Section III - Ownership Information

#### Type of Ownership

- [ ] Publicly Held Corporation
- [ ] Closely Held Corporation
- [ ] Limited Liability Company
- [ ] Charitable Organization—501(c)(3)
- [ ] Sole Proprietorship
- [ ] Government
- [ ] Partnership – General
- [ ] Professional Corporation or Association
- [ ] Professional Limited Liability Company
- [ ] Partnership – Other, Including Limited Liability Partnership and Limited Partnership
- [ ] Other: __________________________

List the state of incorporation or state of organization (except Partnership – General or Sole Proprietorship). Business entities organized under non-U.S. laws list the country of organization.

- [ ] N/A (Partnership – General or Sole Proprietorship)

**State or Country:**

List name and address of the applicant’s registered agent for service of process in Florida (except Sole Proprietorship or Partnership – General) and provide documentation, such as a printout from the Florida Department of State, Division of Corporations' webpage, that the applicant's registered agent is registered with the Florida Department of State, Division of Corporations.

- [ ] N/A (Partnership – General or Sole Proprietorship)

**Name:**

**Address:**

City: __________________________

State: __________________________

Zip Code (+4 optional): __________________________

List the name, position/title, social security number, date of birth and address of each owner, partner, member, manager, officer, director, chief executive, or other person who directly or indirectly controls the operation of the business entity, as applicable. For example, corporations would list officers and directors, limited liability companies would list members and managers, etc.

<table>
<thead>
<tr>
<th></th>
<th>Name &amp; Title</th>
<th>Social Security #</th>
<th>Date of Birth</th>
<th>% of Ownership</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Street Address</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>Social Security #</td>
<td>Date of Birth</td>
<td>% of Ownership</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Name &amp; Title</td>
<td>Social Security #</td>
<td>Date of Birth</td>
<td>% of Ownership</td>
<td></td>
</tr>
<tr>
<td>--------------</td>
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<td></td>
</tr>
<tr>
<td>Street Address</td>
<td>City</td>
<td>State</td>
<td>Zip Code</td>
<td></td>
</tr>
</tbody>
</table>

List the name, social security number, date of birth and address of each person who owns 10 percent or more of the outstanding stock or equity interest in the business entity.

<table>
<thead>
<tr>
<th>Name</th>
<th>Social Security #</th>
<th>Date of Birth</th>
<th>% of Ownership</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street Address</td>
<td>City</td>
<td>State</td>
<td>Zip Code</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
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<tr>
<td>Street Address</td>
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<td>Zip Code</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Social Security #</th>
<th>Date of Birth</th>
<th>% of Ownership</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street Address</td>
<td>City</td>
<td>State</td>
<td>Zip Code</td>
</tr>
</tbody>
</table>
List all trade or business names used by the applicant. Use additional sheet(s) if necessary. If the applicant does not use other trade or business names check this box ☐ and write N/A on the lines below.

Is the applicant a subsidiary of another company? (If yes, provide a listing of all parent companies with percentages of ownership, using additional sheet(s) if necessary). Note: A permit issued pursuant to this application is only valid for the applicant, and the applicant's name and address. (If no, please check this box ☐ and write "N/A" in the lines below).

<table>
<thead>
<tr>
<th>Name</th>
<th>Social Security #:</th>
<th>Date of Birth</th>
<th>% of Ownership</th>
</tr>
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<tbody>
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</table>
### BACKGROUND QUESTIONS

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>☐</td>
<td>☑ Has the applicant or any &quot;affiliated party&quot; (defined below) been found guilty of (regardless of adjudication), or pled nolo contendere to, in any jurisdiction, a violation of law that directly relates to a drug, device, or cosmetic?</td>
</tr>
</tbody>
</table>
| 2. | ☐ | ☑ Has the applicant or any affiliated party (defined below) been fined or disciplined by a regulatory agency in any state (including Florida) for any offense that would constitute a violation of Chapter 499, F.S.?
| 3. | ☐ | ☑ Has the applicant or any affiliated party (defined below) been convicted (regardless of adjudication) of any felony under a federal, state (including Florida), or local law? |
| 4. | ☐ | ☑ Has the applicant or any affiliated party (defined below) been denied a permit or license in any state (including Florida) related to an activity regulated under Chapters 456, 465, 499, or 893, F.S.?
| 5. | ☐ | ☑ Has the applicant or any affiliated party (defined below) had any current or previous permit or license suspended or revoked which was issued by a federal, state, or local governmental agency relating to the manufacture or distribution of drugs, devices, or cosmetics? |
| 6. | ☐ | ☑ Has the applicant or any affiliated party (defined below) ever held a permit issued under Chapter 499, F.S. in a different name than the applicant's name? (If yes, provide the names in which each permit was issued and at what address). |

The term "affiliated party" means: (a) a director, officer, trustee, partner, or committee member of a permittee or applicant or a subsidiary or service corporation of the permittee or applicant; (b) a person who, directly or indirectly, manages, controls, or oversees the operation of a permittee or applicant, regardless of whether such person is a partner, shareholder, manager, member, officer, director, independent contractor, or employee of the permittee or applicant; (c) a person who has filed or is required to file a personal information statement pursuant to s. 499.012(9) or is required to be identified in an application for a permit or to renew a permit pursuant to s. 499.012(8); or (d) the five largest natural shareholders that own at least 5 percent of the permittee or applicant.

If you answered "YES" to any questions in Section IV, you must provide detailed explanations in Section V, including requirements for submitting supporting legal documents. If needed, explain on separate sheet(s).

### Section V – Explanation(s) for "Yes" response(s) to background question(s) in Section IV

<table>
<thead>
<tr>
<th>EXPLANATION</th>
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DBPR-DDC-204 - Application for Permit as a Medical Gas Manufacturer
Incorporated by rule(s): 61N-2.008, F.A.C.
Eff. Date: April 2016
Page 7 of 11
Section VI – Other Permits or Licenses

<table>
<thead>
<tr>
<th>PERMITS OR LICENSES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Are there any other permits or licenses issued by any agency of the State of Florida that authorize the purchase or possession of prescription drugs at the applicant's establishment or address? (If no, please check this box and write &quot;N/A&quot; in the lines below).</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>Permit/License Name</td>
</tr>
<tr>
<td>---------------------</td>
</tr>
</tbody>
</table>

Section VII – Medical Gas Manufacturing Activity

<table>
<thead>
<tr>
<th>MANUFACTURING ACTIVITIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify the types of products the applicant will manufacture or distribute under this permit.</td>
</tr>
<tr>
<td>Oxygen</td>
</tr>
</tbody>
</table>

Generally identify the applicant's intended customers, the persons and entities that will purchase or receive products from the applicant after permit issuance.

<table>
<thead>
<tr>
<th>Manufacturers</th>
<th>Wholesalers</th>
<th>Pharmacies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitals</td>
<td>Practitioners</td>
<td>Clinics</td>
</tr>
<tr>
<td>Veterinarians</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (explain)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

DBPR-204 - Application for Permit as a Medical Gas Manufacturer
Incorporated by rule(s): 61N-2, 008, F.A.C.
Eff. Date: April 2016
Page 8 of 11
Provide your Federal Food and Drug Administration (FDA) establishment registration number.

- [ ] FDA Establishment Registration Number: _____________________________
  or
- [ ] No FDA Establishment Number

1. Are products to be distributed under this permit intended for export?  
   - [ ] Yes  [ ] No

2. Will all required records stored and maintained at applicant’s physical address?  
   (If no, provide the address of the establishments where all required records will be stored and maintained under question #2a.)  
   - [ ] Yes  [ ] No

   2a. Physical address where required records are to be stored:  
       Street Address:
       City:  
       State:  
       Zip Code (+4 optional):  

3. Will the required records be computerized, automated or stored electronically?  
   - [ ] Yes  [ ] No

   If yes, will you have a back-up procedure to be able to provide required records?  
   - [ ] Yes  [ ] No

4. Is there a quarantine area at the applicant’s establishment?  
   Explanation included?  [ ] Yes  [ ] No

5. Is the applicant’s establishment equipped with an alarm system to detect entry after hours and a security system protecting against theft and diversion?  
   (If yes, provide a written description of the alarm and security systems, that include: the type of system and how the system is monitored)  
   Description included?  [ ] Yes  [ ] No  [ ] N/A  

   (If no, provide a written explanation of why the establishment is not equipped with an alarm or security system.)  
   Explanation included?  [ ] Yes  [ ] No  [ ] N/A  

6. Are you submitting a product registration application and labels of your products with this application?  (If no, explain on a separate sheet providing accurate details).  
   [ ] Yes  [ ] No

   Note: You **CAN NOT SELL** a product that you manufacture at the establishment until that product has been registered with the department. Selling a product before it is registered with the division is the basis for application permit denial and enforcement action by the division.  
   Explanation included?  [ ] Yes  [ ] No  [ ] N/A

7. Do you have labels of your products ready for inspection?  
   [ ] Yes  [ ] No

8. Do you intend to comply with all Federal and State "Current Good Manufacturing Practices"?  
   [ ] Yes  [ ] No

9. Will you possess medical gases at your establishment?  (If yes, attach a copy of your most recent fire inspection.)  
   [ ] Yes  [ ] No

10. Do you intend to handle gases not filled by you?  (If yes, you must also be permitted by the division as a Medical Gas Wholesale Distributor.)  
    [ ] Yes  [ ] No

11. Do you intend to sell oxygen to patients?  (If yes, you must be physically located in Florida and be permitted by the division as a Medical Oxygen Retail Establishment.)  
    [ ] Yes  [ ] No

12. Does the applicant have written policies and procedures to include: the receipt, security, storage, inventory, distribution/disposition of prescription drugs; distributing oldest approved stock first (FIFO); identifying, recording and reporting prescription drug losses and thefts; maintenance, retrieval and retention of required records; prescription drug recalls and withdrawals; natural
disasters and other emergencies; segregation and destruction of outdated products; temperature and humidity monitoring?

(If no, provide written explanation for lack of specific policy or procedure identified above).

<table>
<thead>
<tr>
<th>Explanation attached?</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</table>

(If yes, provide a copy of each policy and procedure. Label each policy and procedure specifically identifying the subject matter in the list above that is covered by the policy or procedure. For example, the policy or procedure for receipt, security, storage, inventory could be labeled or identified as “Policy and/or Procedure for receipt, security, storage, inventory” or in another manner similar to this example).

<table>
<thead>
<tr>
<th>Policies attached?</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policies labeled?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
</tbody>
</table>

| 13. Does applicant intend to claim an exemption from inspection by the department? If applicant answered yes to this question applicant must provide: (a) proof applicant is registered with the United States Food and Drug Administration under s. 510 of the federal act, such as a copy of the Internet verification page; AND (b) proof of inspection by the Food and Drug Administration within the past 3 years that demonstrates substantial compliance with good manufacturing practices applicable to medical gases. |
|------------------|-----------------|
| Proof of FDA registration under s. 510 attached? | Yes | No | N/A |
| FDA inspection within last 3 years attached? | Yes | No | N/A |

| 14. Provide the date the establishment will be ready and available for inspection if you are not eligible for an exemption authorized by section 499.93(3), Florida Statutes. This is the earliest date the application may be deemed complete. |
|-----------------|----------|
| / /20 |
Pursuant to s. 559.79, F.S., each application for a license or renewal of a license issued by the Department of Business and Professional Regulation shall be signed under oath or affirmation by the applicant, or owner or chief executive of the applicant without the need for witnesses unless otherwise required by law.

Pursuant to s. 559.791, F.S., any license issued by the Department of Business and Professional Regulation which is issued or renewed in response to an application upon which the person signing under oath or affirmation has falsely sworn to a material statement, including, but not limited to, the names and addresses of the owners or managers of the licensees or applicant, shall be subject to denial of the application or suspension or revocation of the license, and the person falsely swearing shall be subject to any other penalties provided by law.

I UNDERSTAND THAT THE ISSUANCE OF A PERMIT BY THE DEPARTMENT ONLY AUTHORIZES THE APPLICANT TO CONDUCT REGULATED ACTIVITIES IN THE STATE OF FLORIDA UNDER THE NAME IN WHICH THE PERMIT IS ISSUED. IF THE PERMIT IS ISSUED IN THE NAME OF A DBA OR D/B/A THE APPLICANT MAY ONLY CONDUCT BUSINESS IN FLORIDA IN THE NAME OF THE DBA OR D/B/A.

I FURTHER UNDERSTAND THAT PROVIDING ADDITIONAL DBA OR D/B/A NAMES TO THE DEPARTMENT AS PART OF THE APPLICATION PROCESS IS NOT, UPON LICENSURE, AN AUTHORIZATION TO CONDUCT BUSINESS IN FLORIDA UNDER THE NAME OF THOSE ADDITIONAL DBA'S OR D/B/A'S.

I certify that I am empowered to execute this application as required by s. 559.79, F.S. I understand that my signature on this application has the same legal effect as if made under oath. To the best of my knowledge, all information contained on this application is true and correct. I understand the falsification of any information on this application may result in administrative action, including a fine, suspension, or revocation of the license.

| Signature of Applicant, Owner or Chief Executive: | Date: |
| Print Name: | Title: |

Mail completed application to:

Department of Business and Professional Regulation
1940 North Monroe Street
Tallahassee, FL 32399
61N-2.009 Application for Medical Gas Wholesale Distributor Permit

A medical gas wholesale distributor permit is required for wholesale distribution, whether within or into this state. A person, prior to engaging in activity for which a medical gas wholesale distributor permit is required, must file with the department a completed application on form number DBPR-DDC-217. Application for Permit as a Medical Gas Wholesale Distributor, effective April 2016, adopted and incorporated herein by reference and comply with all the requirements for permitting in Chapter 499, F.S. and Rule 61N, F.A.C. This form is available upon request from the Division of Drugs, Devices and Cosmetics at 1940 N. Monroe Street, Tallahassee, Florida 32399. (850) 717-1800, or at http://www.firules.org/Gateway/reference.asp?No=Ref-06910

Rulemaking Authority 499.831, 499.832, 499.834 FS, Law Implemented 499.81, 499.83, 499.831, 499.832, 499.833, 499.834, 499.84, 499.85, 499.86, 499.87, 499.88, 499.89, 499.90, 499.91, 499.92, 499.93, 499.931, 499.94 FS, History—New
State of Florida  
Department of Business and Professional Regulation  
Division of Drugs, Devices, and Cosmetics  

Application for Permit as a Medical Gas Wholesale Distributor  
Form No.: DBPR-DDC-217  

APPLICATION CHECKLIST – IMPORTANT – Submit all items on the checklist below with your application to ensure faster processing.  

<table>
<thead>
<tr>
<th>APPLICATION REQUIREMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enclose the fee of $750.00, which includes $600.00 biennial application fee and $150.00 initial application/on-site inspection fee. If the applicant is providing an inspection report as set forth in Section VI, the applicant would submit a fee of $600.00.</td>
</tr>
<tr>
<td>Make cashier’s check, corporate or business check, or money order payable to the Florida Department of Business and Professional Regulation.</td>
</tr>
<tr>
<td>If you take possession of medical gases at your establishment, provide a photocopy of the establishment’s current fire inspection report.</td>
</tr>
<tr>
<td>If the applicant answered “Yes” to any question in Section IV, enclose a detailed explanation along with any relevant documentation.</td>
</tr>
<tr>
<td>Sign and date the Affidavit section of the application.</td>
</tr>
</tbody>
</table>

Submit the completed application with enclosures to:  
Department of Business and Professional Regulation  
1940 North Monroe Street  
Tallahassee, FL 32399  

PLEASE NOTE:  
Telephone, email, and fax contact information is used to quickly resolve questions with applications. If such information is not provided, questions regarding applications will be mailed to the application contact’s mailing address and may take longer to resolve.
State of Florida
Department of Business and Professional Regulation
Division of Drugs, Devices, and Cosmetics

Application for Permit as a Medical Gas Wholesale Distributor
Form No.: DBPR-DDC-217

If you have any questions or need assistance in completing this application, please contact the Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics, at 850.717.1800. For additional information see the instructions at the beginning of this application.

Section I – Application Type

CHECK ONE OF THE APPLICATION TYPES

☐ New Application [3331/1020]
☐ New Application due to change in ownership. If checked, provide legal documentation for the change of ownership (i.e. Bill of Sale, stock transfer, merger). [3331/1020]

Current Permit Number: ______________________

Section II – Applicant Information

APPLICANT INFORMATION

TAXPAYER IDENTIFICATION NUMBER OR FEDERAL EMPLOYER IDENTIFICATION NUMBER

This is a unique nine-digit number assigned by the Internal Revenue Service (IRS) to business entities operating in the United States for the purposes of identification. When the number is used for identification rather than employment tax reporting, it is usually referred to as a Taxpayer Identification Number (TIN), and when used for the purposes of reporting employment taxes, it is usually referred to as the Federal Employer Identification Number (FEIN).

Applicant’s TIN/FEIN: ______________________

FULL LEGAL NAME

The “full legal name” is the complete name of the business entity that will be operating the establishment. This is generally the name that is on the documents that establish the existence of formation of the business entity. For example, a corporation’s full legal name would normally be the name that is found in the corporation’s articles of incorporation.

Applicant’s Full Legal Name: ______________________

FICTIONOUS, TRADE, OR BUSINESS NAME

If the applicant intends to operate the permitted establishment under a name that is different from the Applicant’s Full Legal Name listed above — e.g. fictitious, trade, or business name (also commonly referred to as a “dba”, “D/B/A”, or “doing business as” name — this name must be registered with the Florida Department of State, Division of Corporations. This is the name that will appear on the permit issued to the applicant by the department and must be the name that the applicant uses on operational documents for permitted activities.

☐ The applicant WILL NOT operate the permitted establishment under a name that is different from the Applicant’s Full Legal Name listed above.
☐ The applicant WILL operate the permitted establishment under the following fictitious, trade, or business name:

[Space for fictitious, trade, or business name]

The fictitious, trade, or business name listed directly above, is registered with the Florida Department of State, Division of Corporations and the applicant has been issued the following registration number:

[Space for registration number]
### Applicant's Mailing Address

<table>
<thead>
<tr>
<th>Street Address or P.O. Box:</th>
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<tbody>
<tr>
<td>City:</td>
<td>State:</td>
</tr>
</tbody>
</table>

### Physical Address of Establishment to be Permitted

(only if different from mailing address) Check [ ] if not applicable

<table>
<thead>
<tr>
<th>Street Address:</th>
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<tbody>
<tr>
<td>City:</td>
<td>State:</td>
</tr>
</tbody>
</table>

#### E-Mail Address:

| E-Mail Address: | Phone Number: | Fax Number: |

### Application Contact

The application contact is the person that the department will contact if there are questions regarding the responses provided on, or the documentation submitted with, the application. The application contact is also the person that will receive all official communication from the department regarding the application.

<table>
<thead>
<tr>
<th>Last/Surname:</th>
<th>First:</th>
<th>Middle:</th>
<th>Suffix:</th>
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</thead>
<tbody>
<tr>
<td>Address:</td>
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</tbody>
</table>

| City: | State: | Zip Code (+4 optional): |

<table>
<thead>
<tr>
<th>Telephone Number:</th>
<th>Fax Number:</th>
</tr>
</thead>
</table>

| E-Mail Address: |  |

### Emergency Contact

The emergency contact is the person that the department will contact in the case of an emergency. During an emergency, the department will contact this person at times outside of the regular business hours listed below. The contact information provided should be sufficient for the department to actually reach and communicate with the person listed in the event of an emergency.

<table>
<thead>
<tr>
<th>Last/Surname:</th>
<th>First:</th>
<th>Middle:</th>
<th>Suffix:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Position/Title:</th>
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<th>Street Address:</th>
<th></th>
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<tbody>
<tr>
<td>City:</td>
<td>State:</td>
</tr>
</tbody>
</table>

| Phone Number: | E-Mail Address: |  |

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DBPR-DDC-217 - Application for Permit as a Medical Gas Wholesale Distributor
Incorporated by rule(s): 61N-2.009, F.A.C.
Eff. Date: April 2016
Page 3 of 10
OPERATING HOURS

List the establishment's daily hours of operation in terms of Eastern Time. REMEMBER to circle "a.m." or "p.m." for each time indicated below.

<table>
<thead>
<tr>
<th>Day</th>
<th>a.m./p.m. to a.m./p.m.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mon</td>
<td><em><strong>:</strong></em> <em><strong>:</strong></em></td>
</tr>
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<td>Tue</td>
<td><em><strong>:</strong></em> <em><strong>:</strong></em></td>
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<td>Wed</td>
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<td>Thu</td>
<td><em><strong>:</strong></em> <em><strong>:</strong></em></td>
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<td>Fri</td>
<td><em><strong>:</strong></em> <em><strong>:</strong></em></td>
</tr>
<tr>
<td>Sat</td>
<td><em><strong>:</strong></em> <em><strong>:</strong></em></td>
</tr>
<tr>
<td>Sun</td>
<td><em><strong>:</strong></em> <em><strong>:</strong></em></td>
</tr>
</tbody>
</table>

Section III – Ownership Information

TYPE OF OWNERSHIP

- Publicly Held Corporation
- Closely Held Corporation
- Limited Liability Company
- Charitable Organization—501(c)(3)
- Sole Proprietorship
- Government
- Partnership – General
- Professional Corporation or Association
- Professional Limited Liability Company
- Partnership – Other, Including Limited Liability Partnership and Limited Partnership
- Other: ____________________________

List the state of incorporation or state of organization (except Partnership—General or Sole Proprietorship). Business entities organized under non-U.S. laws list the country of organization.

- N/A (Partnership—General or Sole Proprietorship)

State or Country:

List name and address of the applicant's registered agent for service of process in Florida (except Sole Proprietorship or Partnership—General) and provide documentation, such as a print out from the Florida Department of State, Division of Corporations' webpage, that the applicant's registered agent is registered with the Florida Department of State, Division of Corporations.

- N/A (Partnership—General or Sole Proprietorship)

Name:

Address:

City: ____________________________ State: ____________________________ Zip Code (+4 Optional): ____________________________

List the name, position/title, social security number, date of birth and address of each owner, partner, member, manager, officer, director, chief executive, or other person who directly or indirectly controls the operation of the business entity, as applicable. For example, corporations would list officers and directors, limited liability companies would list members and managers, etc.

1. Name & Title: ____________________________ Social Security #: ____________________________ Date of Birth: ____________________________ % of Ownership: ____________________________
   Street Address: ____________________________ City: ____________________________ State: ____________________________ Zip Code: ____________________________

2. Name & Title: ____________________________ Social Security #: ____________________________ Date of Birth: ____________________________ % of Ownership: ____________________________
<table>
<thead>
<tr>
<th>Street Address</th>
<th>City</th>
<th>State</th>
<th>Zip Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Name &amp; Title</td>
<td>Social Security #:</td>
<td>Date of Birth:</td>
<td>% of Ownership:</td>
</tr>
<tr>
<td>Street Address</td>
<td>City</td>
<td>State</td>
<td>Zip Code</td>
</tr>
<tr>
<td>4. Name &amp; Title</td>
<td>Social Security #:</td>
<td>Date of Birth:</td>
<td>% of Ownership:</td>
</tr>
<tr>
<td>Street Address</td>
<td>City</td>
<td>State</td>
<td>Zip Code</td>
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<tr>
<td>5. Name &amp; Title</td>
<td>Social Security #:</td>
<td>Date of Birth:</td>
<td>% of Ownership:</td>
</tr>
<tr>
<td>Street Address</td>
<td>City</td>
<td>State</td>
<td>Zip Code</td>
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<tr>
<td>6. Name &amp; Title</td>
<td>Social Security #:</td>
<td>Date of Birth:</td>
<td>% of Ownership:</td>
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<tr>
<td>Street Address</td>
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<tr>
<td>7. Name &amp; Title</td>
<td>Social Security #:</td>
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<td>8. Name &amp; Title</td>
<td>Social Security #:</td>
<td>Date of Birth:</td>
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<td>City</td>
<td>State</td>
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</tbody>
</table>

List the name, social security number, date of birth and address of each person who owns 10 percent or more of the outstanding stock or equity interest in the business entity.

<table>
<thead>
<tr>
<th>Name</th>
<th>Social Security #:</th>
<th>Date of Birth:</th>
<th>% of Ownership:</th>
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<tbody>
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<td>Street Address</td>
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<td>2.</td>
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</table>

DBPR-DDC-217 - Application for Permit as a Medical Gas Wholesale Distributor
Incorporated by rule(s): 61N-2.009, F.A.C.
Eff. Date: April 2016
Page 5 of 10
<table>
<thead>
<tr>
<th></th>
<th>Name:</th>
<th>Social Security #:</th>
<th>Date of Birth:</th>
<th>% of Ownership:</th>
</tr>
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<td></td>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
</tr>
</tbody>
</table>

List all trade or business names used by the applicant. Use additional sheet(s) if necessary. If the applicant does not use other trade or business names check this box [ ] and write N/A on the lines below.

Is the applicant a subsidiary of another company? (If yes, provide a listing of all parent companies with percentages of ownership, using additional sheet(s) if necessary). Note: A permit issued pursuant to this application is only valid for the applicant, and the applicant's name and address. (If no, please check this box [ ] and write "N/A" in the lines below).

Parent Company Name | % of Ownership:
### Section IV – Background Questions

<p>| | | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>BACKGROUND QUESTIONS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>☐ Yes</td>
<td>☐ No</td>
</tr>
<tr>
<td></td>
<td>If yes, explain in detail in Section V</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Has the applicant or any “affiliated party” (defined below) been found guilty of (regardless of adjudication), or pled nolo contendere to, in any jurisdiction, a violation of law that directly relates to a drug, device, or cosmetic?</td>
</tr>
<tr>
<td>2.</td>
<td>☐ Yes</td>
<td>☐ No</td>
</tr>
<tr>
<td></td>
<td>If yes, explain in detail in Section V</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Has the applicant or any affiliated party (defined below) been fined or disciplined by a regulatory agency in any state (including Florida) for any offense that would constitute a violation of Chapter 499, F.S.?</td>
</tr>
<tr>
<td>3.</td>
<td>☐ Yes</td>
<td>☐ No</td>
</tr>
<tr>
<td></td>
<td>If yes, explain in detail in Section V</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Has the applicant or any affiliated party (defined below) been convicted (regardless of adjudication) of any felony under a federal, state (including Florida), or local law?</td>
</tr>
<tr>
<td>4.</td>
<td>☐ Yes</td>
<td>☐ No</td>
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<tr>
<td></td>
<td>If yes, explain in detail in Section V</td>
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<tr>
<td></td>
<td></td>
<td>Has the applicant or any affiliated party (defined below) been denied a permit or license in any state (including Florida) related to an activity regulated under Chapters 456, 465, 499, or 893, F.S.?</td>
</tr>
<tr>
<td>5.</td>
<td>☐ Yes</td>
<td>☐ No</td>
</tr>
<tr>
<td></td>
<td>If yes, explain in detail in Section V</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Has the applicant or any affiliated party (defined below) had any current or previous permit or license suspended or revoked which was issued by a federal, state, or local governmental agency relating to the manufacture or distribution of drugs, devices, or cosmetics?</td>
</tr>
<tr>
<td>6.</td>
<td>☐ Yes</td>
<td>☐ No</td>
</tr>
<tr>
<td></td>
<td>If yes, explain in detail in Section V</td>
<td></td>
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<tr>
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<td></td>
<td>Has the applicant or any affiliated party (defined below) ever held a permit issued under Chapter 499, F.S., in a different name than the applicant’s name? (If yes, provide the names in which each permit was issued and at what address).</td>
</tr>
</tbody>
</table>

The term “affiliated party” means: (a) a director, officer, trustee, partner, or committee member of a permittee or applicant or a subsidiary or service corporation of the permittee or applicant; (b) a person who, directly or indirectly, manages, controls, or oversees the operation of a permittee or applicant, regardless of whether such person is a partner, shareholder, manager, member, officer, director, independent contractor, or employee of the permittee or applicant; (c) a person who has filed or is required to file a personal information statement pursuant to s. 499.012(9) or is required to be identified in an application for a permit or to renew a permit pursuant to s. 499.012(8); or (d) the five largest natural shareholders that own at least 5 percent of the permittee or applicant.

If you answered “YES” to any questions in Section IV, you must provide detailed explanations in Section V, including requirements for submitting supporting legal documents. If needed, explain on separate sheet(s).

### Section V – Explanation(s) for “Yes” response(s) to background question(s) in Section IV

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>EXPLANATION</strong></td>
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</table>

DBPR-DDC-217 - Application for Permit as a Medical Gas Wholesale Distributor
Incorporated by rule(s): 61N-2.009, F.A.C.
Eff. Date: April 2016
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### Section VI – Other Permits or Licenses

#### PERMITS OR LICENSES

1. Are there any other permits or licenses issued by any agency of the State of Florida that authorize the purchase or possession of prescription drugs at the applicant’s establishment or address? (If no, please check this box □ and write “N/A” in the lines below).

<table>
<thead>
<tr>
<th>Permit/License Name</th>
<th>Permit/License Type</th>
<th>Permit/License Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

2. Is the establishment you are seeking to permit located in a state other than Florida? If yes, provide proof that the establishment is legally authorized to engage in the wholesale distribution of medical gases as a wholesale distributor in the state of residence by providing a copy of the resident state license authorizing the wholesale distribution of medical gases.

- Resident State License Attached? □ Yes □ No □ N/A

2a. Has the establishment been inspected by the resident state regulatory body responsible for wholesale distribution of medical gases or by the U.S. Food and Drug Administration in the past 3 years for compliance with current good manufacturing practices? If so, please provide a copy of the inspection report.

- Inspection Report Attached? □ Yes □ No □ N/A

---

### Section VII - Medical Gas Distribution Activity

#### DISTRIBUTION ACTIVITIES

Generally identify the applicant’s intended customers, the persons and entities that will purchase or receive products from the applicant after permit issuance:

- □ Manufacturers
- □ Hospitals
- □ Veterinarians
- □ Other (explain)
- □ Wholesalers
- □ Practitioners
- □ Pharmacies
- □ Clinics

1. Are products to be distributed under this permit intended for export? (Note: A permit may be required for freight forwarders handling products in Florida.)

- □ Yes □ No

2. Will all required records be stored and maintained at applicant’s physical address? (If no, provide the address of the establishments where all required records will be stored and maintained under question #3).

- □ Yes □ No
3. Physical address where required records will be stored:

<table>
<thead>
<tr>
<th>City:</th>
<th>State:</th>
<th>Zip Code (+4 optional):</th>
</tr>
</thead>
</table>

4. Will the required records be computerized, automated or stored electronically?
   If yes, will you have a back-up procedure to be able to provide required records?
   - Yes
   - No

5. Is the applicant's establishment equipped with an alarm system to detect entry after hours and a security system protecting against theft and diversion?
   (If yes, provide a written description of the alarm and security systems, that include: the type of system and how the system is monitored)
   - Description included? Yes
   - No
   - N/A
   (If no, provide a written explanation of why the establishment is not equipped with an alarm or security system.)
   - Explanation included? Yes
   - No
   - N/A

6. Is there a quarantine area at the applicant's establishment?
   If no, provide a written explanation of why the establishment does not have a quarantine area.
   - Explanation included? Yes
   - No
   - N/A

7. Is the applicant's establishment equipped with adequate climate controls (including refrigerated and freezing storage if appropriate for the applicant's distributed products) to ensure safe storage?
   - Yes
   - No

8. Does the applicant intend to take possession of medical gases? (If yes, provide a copy of the most recent fire inspection report for your premises for the purpose of storing medical gases.)
   - Yes
   - No

9. Do you intend to sell oxygen to patients? (If yes, you must be physically located in Florida and be permitted by the division as a Medical Oxygen Retail Establishment.)
   - Yes
   - No

10. Does the applicant intend to fill medical gas containers and sell those to non-patients? (If yes, you must be permitted as a Medical Gas Manufacturer.)
    - Yes
    - No

11. Does the applicant have written policies and procedures to include: the receipt, security, storage, inventory, distribution/disposition of prescription drugs; distributing oldest approved stock first (FIFO); identifying, recording and reporting prescription drug losses and thefts; maintenance, retrieval and retention of required records; prescription drug recalls and withdrawals; natural disasters and other emergencies; segregation and destruction of outdated products; temperature and humidity monitoring?
    (If no, provide written explanation for lack of specific policy or procedure identified above).
    - Explanation attached? Yes
    - No
    - N/A

    (If yes, provide a copy of each policy and procedure. Label each policy and procedure specifically identifying the subject matter in the list above that is covered by the policy or procedure. For example, the policy or procedure for receipt, security, storage, inventory could be labeled or identified as "Policy and/or Procedure for receipt, security, storage, inventory" or in another manner similar to this example.

    - Policies attached? Yes
    - No
    - N/A

    - Policies labeled? Yes
    - No
    - N/A
Section VIII – Affidavit

AFFIDAVIT

Pursuant to s. 559.79, F.S., each application for a license or renewal of a license issued by the Department of Business and Professional Regulation shall be signed under oath or affirmation by the applicant, or owner or chief executive of the applicant without the need for witnesses unless otherwise required by law.

Pursuant to s. 559.791, F.S., any license issued by the Department of Business and Professional Regulation which is issued or renewed in response to an application upon which the person signing under oath or affirmation has falsely sworn to a material statement, including, but not limited to, the names and addresses of the owners or managers of the licensee or applicant, shall be subject to denial of the application or suspension or revocation of the license, and the person falsely swearing shall be subject to any other penalties provided by law.

I UNDERSTAND THAT THE ISSUANCE OF A PERMIT BY THE DEPARTMENT ONLY AUTHORIZES THE APPLICANT TO CONDUCT REGULATED ACTIVITIES IN THE STATE OF FLORIDA UNDER THE NAME IN WHICH THE PERMIT IS ISSUED. IF THE PERMIT IS ISSUED IN THE NAME OF A DBA OR D/B/A THE APPLICANT MAY ONLY CONDUCT BUSINESS IN FLORIDA IN THE NAME OF THE DBA OR D/B/A.

I FURTHER UNDERSTAND THAT PROVIDING ADDITIONAL DBA OR D/B/A NAMES TO THE DEPARTMENT AS PART OF THE APPLICATION PROCESS IS NOT, UPON LICENSURE, AN AUTHORIZATION TO CONDUCT BUSINESS IN FLORIDA UNDER THE NAME OF THOSE ADDITIONAL DBA'S OR D/B/A'S.

I certify that I am empowered to execute this application as required by s. 559.79, F.S. I understand that my signature on this application has the same legal effect as if made under oath. To the best of my knowledge, all information contained on this application is true and correct. I understand the falsification of any information on this application may result in administrative action, including a fine, suspension, or revocation of the license.

Signature of Applicant, Owner or Chief Executive:  
Date:

Print Name:  
Title:

Mail completed application to:

Department of Business and Professional Regulation  
1940 North Monroe Street  
Tallahassee, FL 32399
61N-2.010 Application for Medical Oxygen Retail Establishment Permit

A medical oxygen retail establishment permit is required for an entity that is located in the state and that sells or delivers medical oxygen directly to patients in this state. A person located in this state, other than a pharmacy licensed under chapter 465, prior to engaging in activity for which a medical oxygen retail establishment permit is required, must file with the department a completed application on form number DBPR-DDC-223, Application for Permit as a Medical Oxygen Retail Establishment, effective April 2016, adopted and incorporated herein by reference and comply with all the requirements for permitting in Chapter 499, F.S. and Rule 61N, F.A.C.

This form is available upon request from the Division of Drugs, Devices and Cosmetics at 1940 N. Monroe Street, Tallahassee, Florida 32399, (850)717-1800, or at http://www.firules.org/Gateway/reference.asp?No=Ref-06911

Rulemaking Authority 499.831, 499.832, 499.834 F.S. Law Implemented 499.81, 499.83, 499.831, 499.832, 499.833, 499.834, 499.84, 499.85, 499.86, 499.87, 499.88, 499.89, 499.90, 499.91, 499.92, 499.93, 499.931, 499.94 F.S. History—New
APPLICATION CHECKLIST – IMPORTANT – Submit all items on the checklist below with your application to ensure faster processing.

<table>
<thead>
<tr>
<th>APPLICATION</th>
<th>APPLICATION REQUIREMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application for Permit as a Medical Oxygen Retail Establishment</td>
<td>Submit fee of $750.00, which includes $600.00 biennial application fee and $150.00 initial application/on-site inspection fee.</td>
</tr>
<tr>
<td></td>
<td>Make cashier's check, corporate or business check, or money order payable to the Florida Department of Business and Professional Regulation.</td>
</tr>
<tr>
<td></td>
<td>If you answer &quot;Yes&quot; to any question in Section IV, be sure to provide a detailed explanation along with any relevant documentation.</td>
</tr>
<tr>
<td></td>
<td>If you take possession of medical Oxygen at your establishment, provide a photocopy of the establishment's current fire inspection report.</td>
</tr>
<tr>
<td></td>
<td>Sign and date the Affidavit section of the application.</td>
</tr>
<tr>
<td></td>
<td>Submit the completed application with enclosures to: Department of Business and Professional Regulation 1940 North Monroe Street Tallahassee, FL 32399</td>
</tr>
</tbody>
</table>

PLEASE NOTE: Telephone, email, and fax contact information is used to quickly resolve questions with applications. If such information is not provided, questions regarding applications will be mailed to the application contact’s mailing address and may take longer to resolve.
State of Florida
Department of Business and Professional Regulation
Division of Drugs, Devices, and Cosmetics

Application for Permit as a Medical Oxygen Retail Establishment
Form No.: DBPR-DDC-223

If you have any questions or need assistance in completing this application, please contact the Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics, at 850.717.1800. For additional information see the instructions at the beginning of this application.

Section I – Application Type

<table>
<thead>
<tr>
<th>CHECK ONE OF THE APPLICATION TYPES</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ New Application [3332/1020]</td>
</tr>
<tr>
<td>☐ New Application due to change in ownership. If checked, provide legal documentation for the change of ownership (i.e. Bill of Sale, stock transfer, merger). [3332/1020]</td>
</tr>
<tr>
<td>Current Permit Number: ___________</td>
</tr>
</tbody>
</table>

Section II – Applicant Information

<table>
<thead>
<tr>
<th>APPLICANT INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAXPAYER IDENTIFICATION NUMBER OR FEDERAL EMPLOYER IDENTIFICATION NUMBER</td>
</tr>
<tr>
<td>This is a unique nine-digit number assigned by the Internal Revenue Service (IRS) to business entities operating in the United States for the purposes of identification. When the number is used for identification rather than employment tax reporting, it is usually referred to as a Taxpayer Identification Number (TIN), and when used for the purposes of reporting employment taxes, it is usually referred to as the Federal Employer Identification Number (FEIN).</td>
</tr>
<tr>
<td>Applicant’s TIN/FEIN: ___________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FULL LEGAL NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>The “full legal name” is the complete name of the business entity that will be operating the establishment. This is generally the name that is on the documents that establish the existence or formation of the business entity. For example, a corporation’s full legal name would normally be the name that is found in the corporation’s articles of incorporation.</td>
</tr>
<tr>
<td>Applicant’s Full Legal Name: ___________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FICTITIOUS, TRADE, OR BUSINESS NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>If the applicant intends to operate the permitted establishment under a name that is different from the Applicant’s Full Legal Name listed above – e.g. fictitious, trade, or business name (also commonly referred to as a “d/b/a” or “D/B/A,” or “doing business as” name – this name must be registered with the Florida Department of State, Division of Corporations. This is the name that will appear on the permit issued to the applicant by the department and must be the name that the applicant uses on operational documents for permitted activities.</td>
</tr>
<tr>
<td>☐ The applicant WILL NOT operate the permitted establishment under a name that is different from the Applicant’s Full Legal Name listed above.</td>
</tr>
<tr>
<td>☐ The applicant WILL operate the permitted establishment under the following fictitious, trade, or business name: ___________</td>
</tr>
</tbody>
</table>

The fictitious, trade, or business name listed directly above, is registered with the Florida Department of State, Division of Corporations and the applicant has been issued the following registration number: ___________
APPLICANT'S MAILING ADDRESS

Street Address or P.O. Box:

City: ___________________________ State: ___________ Zip Code (+4 optional): ___________

PHYSICAL ADDRESS OF ESTABLISHMENT TO BE PERMITTED
(only if different from mailing address) Check [ ] if not applicable

Street Address:

City: ___________________________ State: ___________ Zip Code (+4 optional): ___________

County (if located in Florida): ___________ Country: ___________

E-Mail Address: ___________________________ Phone Number: __________________ Fax Number: __________________

APPLICATION CONTACT

The application contact is the person that the department will contact if there are questions regarding the
responses provided on, or the documentation submitted with, the application. The application contact is
also the person that will receive all official communication from the department regarding the application.

Last/Surname: ___________________________ First: ___________ Middle: ___________ Suffix: ___________
Address: ________________________________ ________________________________

City: ___________________________ State: ___________ Zip Code (+4 optional): ___________

Telephone Number: ___________________________ Fax Number: __________________
E-Mail Address: ________________________________

EMERGENCY CONTACT

The emergency contact is the person that the department will contact in the case of an emergency.
During an emergency, the department will contact this person at times outside of the regular business
hours listed below. The contact information provided should be sufficient for the department to actually
reach and communicate with the person listed in the event of an emergency.

Last/Surname: ___________________________ First: ___________ Middle: ___________ Suffix: ___________

Position/Title: ________________________________
Address: ________________________________

City: ___________________________ State: ___________ Zip Code (+4 optional): ___________

Phone Number: ___________________________ E-Mail Address: ___________________________
**OPERATING HOURS**

List the establishment's daily hours of operation in terms of Eastern Time. REMEMBER to circle "a.m." or "p.m." for each time indicated below.

<table>
<thead>
<tr>
<th>Day</th>
<th>Start Time</th>
<th>End Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mon</td>
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<td>Tue</td>
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<td>Fri</td>
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<tr>
<td>Sat</td>
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<tr>
<td>Sun</td>
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</tr>
</tbody>
</table>

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**Section III – Ownership Information**

**TYPE OF OWNERSHIP**

- [ ] Publicly Held Corporation
- [ ] Closely Held Corporation
- [ ] Limited Liability Company
- [ ] Charitable Organization—501(c)(3)
- [ ] Sole Proprietorship
- [ ] Government
- [ ] Partnership – General
- [ ] Professional Corporation or Association
- [ ] Professional Limited Liability Company
- [ ] Partnership – Other, Including Limited Liability Partnership and Limited Partnership
- [ ] Other: ____________________

List the state of incorporation or state of organization (except Partnership – General or Sole Proprietorship). Business entities organized under non-U.S. laws list the country of organization.

- [ ] N/A (Partnership – General or Sole Proprietorship)

State or Country:

List name and address of the applicant's registered agent for service of process in Florida (except Sole Proprietorship or Partnership – General) and provide documentation, such as a print out from the Florida Department of State, Division of Corporations' webpage, that the applicant's registered agent is registered with the Florida Department of State, Division of Corporations.

- [ ] N/A (Partnership – General or Sole Proprietorship)

Name:

Address:

<table>
<thead>
<tr>
<th>City:</th>
<th>State:</th>
<th>Zip Code (+4 optional):</th>
</tr>
</thead>
</table>

Add the name, position/title, social security number, date of birth and address of each owner, partner, member, manager, officer, director, chief executive, or other person who directly or indirectly controls the operation of the business entity, as applicable. For example, corporations would list officers and directors, limited liability companies would list members and managers, etc.

<table>
<thead>
<tr>
<th>Name &amp; Title:</th>
<th>Social Security #:</th>
<th>Date of Birth:</th>
<th>% of Ownership:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name &amp; Title:</th>
<th>Social Security #:</th>
<th>Date of Birth:</th>
<th>% of Ownership:</th>
</tr>
</thead>
</table>

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DBPR-DDC-223 - Application for Permit as a Medical Oxygen Retail Establishment
Incorporated by rule(s): 61N-2.010, F.A.C.
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<table>
<thead>
<tr>
<th>No.</th>
<th>Name &amp; Title</th>
<th>Social Security #</th>
<th>Date of Birth</th>
<th>% of Ownership</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
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<td>2.</td>
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<td>7.</td>
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<td>8.</td>
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</tbody>
</table>

List the name, social security number, date of birth and address of each person who owns 10 percent or more of the outstanding stock or equity interest in the business entity.
<table>
<thead>
<tr>
<th>Name:</th>
<th>Social Security #:</th>
<th>Date of Birth:</th>
<th>% of Ownership:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
</tr>
<tr>
<td>4. Name:</td>
<td>Social Security #:</td>
<td>Date of Birth:</td>
<td>% of Ownership:</td>
</tr>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
</tr>
<tr>
<td>6. Name:</td>
<td>Social Security #:</td>
<td>Date of Birth:</td>
<td>% of Ownership:</td>
</tr>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
</tr>
<tr>
<td>8. Name:</td>
<td>Social Security #:</td>
<td>Date of Birth:</td>
<td>% of Ownership:</td>
</tr>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
</tr>
</tbody>
</table>

List all trade or business names used by the applicant. Use additional sheet(s) if necessary. If the applicant does not use other trade or business names check this box ☐ and write N/A on the lines below.

Is the applicant a subsidiary of another company? (If yes, provide a listing of all parent companies with percentages of ownership, using additional sheet(s) if necessary). Note: A permit issued pursuant to this application is only valid for the applicant, and the applicant's name and address. (If no, please check this box ☐ and write "N/A" in the lines below).

<table>
<thead>
<tr>
<th>Parent Company Name</th>
<th>% of Ownership</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>
Section IV – Background Questions

<table>
<thead>
<tr>
<th>BACKGROUND QUESTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. □ Yes</td>
</tr>
<tr>
<td>If yes, explain in detail in Section V</td>
</tr>
<tr>
<td>2. □ Yes</td>
</tr>
<tr>
<td>If yes, explain in detail in Section V</td>
</tr>
<tr>
<td>3. □ Yes</td>
</tr>
<tr>
<td>If yes, explain in detail in Section V</td>
</tr>
<tr>
<td>4. □ Yes</td>
</tr>
<tr>
<td>If yes, explain in detail in Section V</td>
</tr>
<tr>
<td>5. □ Yes</td>
</tr>
<tr>
<td>If yes, explain in detail in Section V</td>
</tr>
<tr>
<td>6. □ Yes</td>
</tr>
<tr>
<td>If yes, explain in detail in Section V</td>
</tr>
</tbody>
</table>

The term “affiliated party” means: (a) a director, officer, trustee, partner, or committee member of a permittee or applicant or a subsidiary or service corporation of the permittee or applicant; (b) a person who, directly or indirectly, manages, controls, or oversees the operation of a permittee or applicant, regardless of whether such person is a partner, shareholder, manager, member, officer, director, independent contractor, or employee of the permittee or applicant; (c) a person who has filed or is required to file a personal information statement pursuant to s. 499.012(9) or is required to be identified in an application for a permit or to renew a permit pursuant to s. 499.012(8); or (d) the five largest natural shareholders that own at least 5 percent of the permittee or applicant.

If you answered “YES” to any questions in Section IV, you must provide detailed explanations in Section V, including requirements for submitting supporting legal documents. If needed, explain on separate sheet(s).

Section V – Explanation(s) for “Yes” response(s) to background question(s) in Section IV

<table>
<thead>
<tr>
<th>EXPLANATION</th>
</tr>
</thead>
</table>

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Incorporated by rule(s): 61N-2.010, F.A.C.
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### Section V (cont'd)


### Section VI – Other Permits or Licenses

<table>
<thead>
<tr>
<th>PERMITS OR LICENSES</th>
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</thead>
<tbody>
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<td></td>
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</table>

<table>
<thead>
<tr>
<th>1. Are there any other permits or licenses issued by any agency of the State of Florida that authorize the purchase or possession of prescription drugs at the applicant's establishment or address? (If no, please check this box and write &quot;N/A&quot; in the lines below).</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Yes □ No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1a. Permit/License Name</th>
<th>Permit/License Type</th>
<th>Permit/License Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

### Section VII – Medical Oxygen Retail Establishment Activity

<table>
<thead>
<tr>
<th>DISTRIBUTION ACTIVITIES</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

| The Medical Oxygen Retail Establishment permit only authorizes distribution of oxygen to patients with a prescription. |
|                                                                                                                         |
| □ Yes □ No                                                                                                           |

<table>
<thead>
<tr>
<th>1. Will all required records be stored and maintained at applicant's physical address? (If no, provide the address of the establishments where all required records will be stored and maintained under question #1a.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Yes □ No</td>
</tr>
</tbody>
</table>

| 1a. Physical address where required records will be stored: |
| Street Address: |
| City: State: Zip Code (+4 optional): |

<p>| 2. Will the required records be computerized, automated or stored electronically? |
| If yes, will you have a back-up procedure to be able to provide required records? |
| □ Yes □ No |
| □ Yes □ No |</p>
<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.</td>
<td>Will you possess medical oxygen at your establishment? (If yes, attach a copy of your most recent fire inspection.) Fire inspection attached?</td>
<td>☐ Yes</td>
<td>☐ No</td>
<td>☐ N/A</td>
</tr>
<tr>
<td>4.</td>
<td>Does the applicant intend to fill Medical Oxygen Containers? (Answer NO if you intend to have another permit holder fill the tanks.)</td>
<td>☐ Yes</td>
<td>☐ No</td>
<td>☐ N/A</td>
</tr>
<tr>
<td>5.</td>
<td>If you intend to fill Medical Oxygen Containers, please provide your FDA establishment number? (You must provide the FDA establishment number or a copy of the application you submitted to the FDA.) Est. No:</td>
<td>☐ Yes</td>
<td>☐ No</td>
<td>☐ N/A</td>
</tr>
<tr>
<td>6.</td>
<td>If you intend to fill Medical Oxygen Containers, do you have labels of your product ready for inspection?</td>
<td>☐ Yes</td>
<td>☐ No</td>
<td>☐ N/A</td>
</tr>
<tr>
<td>7.</td>
<td>Do you intend to sell medical oxygen you have refilled to a person other than a patient? (If yes, you must also be permitted by the division as a Medical Gas Manufacturer.)</td>
<td>☐ Yes</td>
<td>☐ No</td>
<td>☐ N/A</td>
</tr>
<tr>
<td>8.</td>
<td>What type of Medical Oxygen do you intend to handle (including back-up method for concentrators)?</td>
<td>☐ Gas (vaporized) Oxygen</td>
<td>☐ Liquid Oxygen</td>
<td>☐ Neither</td>
</tr>
<tr>
<td>9.</td>
<td>Is there a quarantine area at the applicant's establishment? (If no, please provide a written explanation). Explanation included?</td>
<td>☐ Yes</td>
<td>☐ No</td>
<td>☐ N/A</td>
</tr>
<tr>
<td>10.</td>
<td>Is the applicant's establishment equipped with an alarm system to detect entry after hours and a security system protecting against theft and diversion? (If yes, provide a written description of the alarm and security systems, that include: the type of system and how the system is monitored). Description included?</td>
<td>☐ Yes</td>
<td>☐ No</td>
<td>☐ N/A</td>
</tr>
<tr>
<td></td>
<td>(If no, provide a written explanation of why the establishment is not equipped with an alarm or security system). Explanation included?</td>
<td>☐ Yes</td>
<td>☐ No</td>
<td>☐ N/A</td>
</tr>
<tr>
<td>11.</td>
<td>Does the applicant have written policies and procedures to include: the receipt, security, storage, inventory, distribution/disposition of prescription drugs; distributing oldest approved stock first (FIFO); identifying, recording and reporting prescription drug losses and thefts; maintenance, retrieval and retention of required records; prescription drug recalls and withdrawals; natural disasters and other emergencies; segregation and destruction of outdated products; temperature and humidity monitoring? (If no, provide written explanation for lack of specific policy or procedure identified above). Explanation attached?</td>
<td>☐ Yes</td>
<td>☐ No</td>
<td>☐ N/A</td>
</tr>
<tr>
<td></td>
<td>If yes, provide a copy of each policy and procedure. Label each policy and procedure specifically identifying the subject matter in the list above that is covered by the policy or procedure. For example, the policy or procedure for receipt, security, storage, inventory could be labeled or identified as “Policy and/or Procedure for receipt, security, storage, inventory&quot; or in another manner similar to this example. Policies attached?</td>
<td>☐ Yes</td>
<td>☐ No</td>
<td>☐ N/A</td>
</tr>
<tr>
<td></td>
<td>Policies labeled?</td>
<td>☐ Yes</td>
<td>☐ No</td>
<td>☐ N/A</td>
</tr>
</tbody>
</table>
12. **Who will be supplying the medical oxygen to your patients?** (Your supplier must hold a Medical Gas Manufacturer or Medical Gas Wholesale Distributor permit to sell to you, and a Medical Oxygen Retail Establishment permit to deliver to your patients).

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>Permit No.</th>
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</table>

13. **If the applicant is not taking possession of medical oxygen, does the applicant have written policies and procedures to include: maintenance, retrieval and retention of required records; prescription drug recalls and withdrawals; and natural disasters and other emergencies?**

(If no, provide written explanation for lack of specific policy or procedure identified above).

- [ ] Yes  [ ] No  [ ] N/A

- **Explanation attached?** [ ] Yes  [ ] No  [ ] N/A

If yes, provide a copy of each policy and procedure. Label each policy and procedure specifically identifying the subject matter in the list above that is covered by the policy or procedure. For example, the policy or procedure for prescription drug recalls could be labeled or identified as "Policy and/or Procedure for prescription drug recalls" or in another manner similar to this example.

- [ ] Yes  [ ] No  [ ] N/A

- **Policies attached?** [ ] Yes  [ ] No  [ ] N/A

- **Policies labeled?** [ ] Yes  [ ] No  [ ] N/A

14. **Does the applicant intend to sell or provide Medical Oxygen Containers purchased from another establishment to a person (including another branch) other than a patient?** (If yes, you will be required to obtain a Medical Gas Wholesale Distributor permit.)

- [ ] Yes  [ ] No

15. **If the applicant uses delivery vehicles, are the vehicles secured with alarm systems?**

- [ ] Yes  [ ] No

16. **Do you understand you must maintain either the original or a copy of the prescription, or order, for each patient?**

- [ ] Yes  [ ] No

17. **Do you understand that the prescription, or order, is only valid for one year from when it was originally filed?**

- [ ] Yes  [ ] No

18. **Provide the date the establishment will be ready and available for inspection. This is the earliest date the application may be deemed complete.**

   /__/20
AFFIDAVIT

Pursuant to s. 559.79, F.S., each application for a license or renewal of a license issued by the Department of Business and Professional Regulation shall be signed under oath or affirmation by the applicant, or owner or chief executive of the applicant without the need for witnesses unless otherwise required by law.

Pursuant to s. 559.791, F.S., any license issued by the Department of Business and Professional Regulation which is issued or renewed in response to an application upon which the person signing under oath or affirmation has falsely sworn to a material statement, including, but not limited to, the names and addresses of the owners or managers of the licensee or applicant, shall be subject to denial of the application or suspension or revocation of the license, and the person falsely swearing shall be subject to any other penalties provided by law.

I UNDERSTAND THAT THE ISSUANCE OF A PERMIT BY THE DEPARTMENT ONLY AUTHORIZES THE APPLICANT TO CONDUCT REGULATED ACTIVITIES IN THE STATE OF FLORIDA UNDER THE NAME IN WHICH THE PERMIT IS IssUED. IF THE PERMIT IS ISSUED IN THE NAME OF A DBA OR D/B/A THE APPLICANT MAY ONLY CONDUCT BUSINESS IN FLORIDA IN THE NAME OF THE DBA OR D/B/A.

I FURTHER UNDERSTAND THAT PROVIDING ADDITIONAL DBA OR D/B/A NAMES TO THE DEPARTMENT AS PART OF THE APPLICATION PROCESS IS NOT, UPON LICENSURE, AN AUTHORIZATION TO CONDUCT BUSINESS IN FLORIDA UNDER THE NAME OF THOSE ADDITIONAL DBA’S OR D/B/A’S.

I certify that I am empowered to execute this application as required by s. 559.79, F.S. I understand that my signature on this application has the same legal effect as if made under oath. To the best of my knowledge, all information contained on this application is true and correct. I understand the falsification of any information on this application may result in administrative action, including a fine, suspension, or revocation of the license.

<table>
<thead>
<tr>
<th>Signature of Applicant, Owner or Chief Executive:</th>
<th>Date:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Print Name:</th>
<th>Title:</th>
</tr>
</thead>
</table>

Mail completed application to:

Department of Business and Professional Regulation
1940 North Monroe Street
Tallahassee, FL 32399
61N-2.013 Application for Over-The-Counter Drug Manufacturer Permit

An over-the-counter drug manufacturer permit is required for any person that engages in the manufacture or repackaging of an over-the-counter drug. A person located in this state, other than a pharmacy operating in compliance with pharmacy practice standards set forth in chapter 465 and the rules promulgated thereunder, engaging in activity for which an over-the-counter drug manufacturer permit is required, must file an application on form number DBPR-DDC-205. Application for Permit as an Over-The-Counter Drug Manufacturer, effective April 2016, adopted and incorporated herein by reference and comply with all the requirements for permitting in Chapter 499, F.S. and Rule 61N, F.A.C. This form is available upon request from the Division of Drugs, Devices and Cosmetics at 1940 N. Monroe Street, Tallahassee, Florida 32399, (850)717-1800, or at http://www.flrules.org/Gateway/reference.asp?No=Ref-06912

Rulemaking Authority 499.012(3) FS. Law Implemented 499.01, 499.012, 499.0121, 499.015, 499.04, 499.041 FS. History-New-
APPLICATION CHECKLIST – IMPORTANT – Submit all items on the checklist below with your application to ensure faster processing.

<table>
<thead>
<tr>
<th>APPLICATION</th>
<th>APPLICATION REQUIREMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application for Permit as an Over-The-Counter Drug Manufacturer</td>
<td>☐ Submit fee of $950.00, which includes $800.00 biennial application fee and $150.00 initial application/on-site inspection fee. If establishment is applying for multiple manufacturing permits in the applicant's name and at applicant's address, you are only required to pay for the permit with the highest fee.</td>
</tr>
<tr>
<td></td>
<td>☐ Make cashier's check, corporate or business check, or money order payable to the Florida Department of Business and Professional Regulation.</td>
</tr>
<tr>
<td></td>
<td>☐ If you answer &quot;Yes&quot; to any question in Section IV, be sure to provide a detailed explanation along with any relevant documentation.</td>
</tr>
<tr>
<td></td>
<td>☐ Sign and date the Affidavit section of the application.</td>
</tr>
<tr>
<td></td>
<td>Submit the completed application with enclosures to:</td>
</tr>
<tr>
<td></td>
<td>Department of Business and Professional Regulation</td>
</tr>
<tr>
<td></td>
<td>1940 North Monroe Street</td>
</tr>
<tr>
<td></td>
<td>Tallahassee, FL 32399</td>
</tr>
</tbody>
</table>

PLEASE NOTE:
Telephone, email, and fax contact information is used to quickly resolve questions with applications. If such information is not provided, questions regarding applications will be mailed to the application contact's mailing address and may take longer to resolve.
State of Florida  
Department of Business and Professional Regulation  
Division of Drugs, Devices, and Cosmetics

Application for Permit as an Over-The-Counter Drug Manufacturer  
Form No.: DBPR-DDC-205

If you have any questions or need assistance in completing this application, please contact the Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics, at 850.717.1800. For additional information see the instructions at the beginning of this application.

Section I – Application Type

CHECK ONE OF THE APPLICATION TYPES

☐ New Application [3321/1020]
☐ New Application due to change in ownership. If checked, provide legal documentation for the change of ownership (i.e. Bill of Sale, stock transfer, merger). [3321/1020]
   Current Permit Number: ____________________________

Section II – Applicant Information

APPLICANT INFORMATION

TAXPAYER IDENTIFICATION NUMBER OR FEDERAL EMPLOYER IDENTIFICATION NUMBER

This is a unique nine-digit number assigned by the Internal Revenue Service (IRS) to business entities operating in the United States for the purposes of identification. When the number is used for identification rather than employment tax reporting, it is usually referred to as a Taxpayer Identification Number (TIN), and when used for the purposes of reporting employment taxes, it is usually referred to as the Federal Employer Identification Number (FEIN).
   Applicant’s TIN/FEIN:

FULL LEGAL NAME

The “full legal name” is the complete name of the business entity that will be operating the establishment. This is generally the name that is on the documents that establish the existence or formation of the business entity. For example, a corporation’s full legal name would normally be the name that is found in the corporation’s articles of incorporation.
   Applicant’s Full Legal Name:

FICTITIOUS, TRADE, OR BUSINESS NAME

If the applicant intends to operate the permitted establishment under a name that is different from the Applicant’s Full Legal Name listed above – e.g. fictitious, trade, or business name (also commonly referred to as a “dba”, “D/B/A”, or “doing business as” name – this name must be registered with the Florida Department of State, Division of Corporations. This is the name that will appear on the permit issued to the applicant by the department and must be the name that the applicant uses on operational documents for permitted activities.

☐ The applicant WILL NOT operate the permitted establishment under a name that is different from the Applicant’s Full Legal Name listed above.
☐ The applicant WILL operate the permitted establishment under the following fictitious, trade, or business name:

   ____________________________________________

   The fictitious, trade, or business name listed directly above, is registered with the Florida Department of State, Division of Corporations and the applicant has been issued the following registration number:
   ____________________________________________

DBPR-DDC-205 - Application for Permit as an Over-The-Counter Drug Manufacturer
Incorporated by rules: 61N-2.013, F.A.C.
Eff. Date: April 2016
Page 2 of 10
### Applicant's Mailing Address

<table>
<thead>
<tr>
<th>Street Address or P.O. Box:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>City:</td>
<td>State:</td>
</tr>
</tbody>
</table>

### Physical Address of Establishment to be Permitted

(only if different from mailing address) Check □ if not applicable

<table>
<thead>
<tr>
<th>Street Address:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>City:</td>
<td>State:</td>
</tr>
<tr>
<td>County (if located in Florida):</td>
<td>Country:</td>
</tr>
<tr>
<td>E-Mail Address:</td>
<td>Phone Number:</td>
</tr>
</tbody>
</table>

### Application Contact

The application contact is the person that the department will contact if there are questions regarding the responses provided on, or the documentation submitted with, the application. The application contact is also the person that will receive all official communication from the department regarding the application.

<table>
<thead>
<tr>
<th>Last/Surname:</th>
<th>First:</th>
<th>Middle:</th>
<th>Suffix:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>City:</td>
<td>State:</td>
<td>Zip Code (+4 optional)</td>
<td></td>
</tr>
</tbody>
</table>

### Telephone Number: | Fax Number: |
|-------------------|------------|

### E-Mail Address: | |

### Emergency Contact

The emergency contact is the person that the department will contact in the case of an emergency. During an emergency, the department will contact this person at times outside of the regular business hours listed below. The contact information provided should be sufficient for the department to actually reach and communicate with the person listed in the event of an emergency.

<table>
<thead>
<tr>
<th>Last/Surname:</th>
<th>First:</th>
<th>Middle:</th>
<th>Suffix:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Position/Title:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Street Address:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>City:</td>
<td>State:</td>
<td>Zip Code (+4 optional)</td>
<td></td>
</tr>
</tbody>
</table>

### Telephone Number: | E-Mail Address: |
|-------------------|-----------------|
### OPERATING HOURS

List the establishment's daily hours of operation in terms of Eastern Time. REMEMBER to circle "a.m." or "p.m." for each time indicated below.

<table>
<thead>
<tr>
<th>Day</th>
<th>Opening</th>
<th>Closing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mon</td>
<td>___ a.m./p.m.</td>
<td>___ a.m./p.m.</td>
</tr>
<tr>
<td>Tue</td>
<td>___ a.m./p.m.</td>
<td>___ a.m./p.m.</td>
</tr>
<tr>
<td>Wed</td>
<td>___ a.m./p.m.</td>
<td>___ a.m./p.m.</td>
</tr>
<tr>
<td>Thu</td>
<td>___ a.m./p.m.</td>
<td>___ a.m./p.m.</td>
</tr>
<tr>
<td>Fri</td>
<td>___ a.m./p.m.</td>
<td>___ a.m./p.m.</td>
</tr>
<tr>
<td>Sat</td>
<td>___ a.m./p.m.</td>
<td>___ a.m./p.m.</td>
</tr>
<tr>
<td>Sun</td>
<td>___ a.m./p.m.</td>
<td>___ a.m./p.m.</td>
</tr>
</tbody>
</table>

### Section III – Ownership Information

#### TYPE OF OWNERSHIP

- [ ] Publicly Held Corporation
- [ ] Closely Held Corporation
- [ ] Limited Liability Company
- [ ] Charitable Organization—501(c)(3)
- [ ] Sole Proprietorship
- [ ] Government
- [ ] Partnership – General
- [ ] Professional Corporation or Association
- [ ] Professional Limited Liability Company
- [ ] Partnership – Other, Including Limited Liability Partnership and Limited Partnership
- [ ] Other: __________

List the state of incorporation or state of organization (except Partnership – General or Sole Proprietorship). Business entities organized under non-U.S. laws list the country of organization.

- [ ] N/A (Partnership – General or Sole Proprietorship)

State or Country: __________

List name and address of the applicant's registered agent for service of process in Florida (except Sole Proprietorship or Partnership – General) and provide documentation, such as a print out from the Florida Department of State, Division of Corporations’ webpage, that the applicant's registered agent is registered with the Florida Department of State, Division of Corporations.

- [ ] N/A (Partnership – General or Sole Proprietorship)

**Name:** __________

**Address:**

- **City:** __________
- **State:** __________
- **Zipcode (+4 optional):** __________

List the name, position/title, social security number, date of birth and address of each owner, partner, member, manager, officer, director, chief executive, or other person who directly or indirectly controls the operation of the business entity, as applicable. For example, corporations would list officers and directors, limited liability companies would list members and managers, etc.

<table>
<thead>
<tr>
<th></th>
<th>Name &amp; Title</th>
<th>Social Security #</th>
<th>Date of Birth</th>
<th>% of Ownership</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
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<td>2</td>
<td></td>
<td>Social Security #:</td>
<td>Date of Birth</td>
<td>% of Ownership</td>
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<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
</tr>
<tr>
<td>No.</td>
<td>Name &amp; Title</td>
<td>Social Security #:</td>
<td>Date of Birth:</td>
<td>% of Ownership:</td>
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<td>Street Address:</td>
<td>City:</td>
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</tbody>
</table>

List the name, social security number, date of birth and address of each person who owns 10 percent or more of the outstanding stock or equity interest in the business entity:

<table>
<thead>
<tr>
<th>No.</th>
<th>Name:</th>
<th>Social Security #:</th>
<th>Date of Birth:</th>
<th>% of Ownership:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
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</tr>
<tr>
<td>Name</td>
<td>Social Security #:</td>
<td>Date of Birth</td>
<td>% of Ownership</td>
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</table>

List all trade or business names used by the applicant. Use additional sheet(s) if necessary. If the applicant does not use other trade or business names check this box ☐ and write N/A on the lines below.

<table>
<thead>
<tr>
<th>Name</th>
<th>Social Security #:</th>
<th>Date of Birth</th>
<th>% of Ownership</th>
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<tbody>
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</table>

Is the applicant a subsidiary of another company? (If yes, provide a listing of all parent companies with percentages of ownership, using additional sheet(s) if necessary). □ Yes □ No

Note: A permit issued pursuant to this application is only valid for the applicant, and the applicant's name and address. (If no, please check this box ☐ and write "N/A" in the lines below).

<table>
<thead>
<tr>
<th>Parent Company Name</th>
<th>% of Ownership</th>
</tr>
</thead>
<tbody>
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### Section IV – Background Questions

**BACKGROUND QUESTIONS**

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>
| 1. | Yes | No | Has the applicant or any “affiliated party” (defined below) been found guilty of (regardless of adjudication), or pled nolo contendere to, in any jurisdiction, a violation of law that directly relates to a drug, device, or cosmetic?  
If yes, explain in detail in Section V |
| 2. | Yes | No | Has the applicant or any affiliated party (defined below) been fined or disciplined by a regulatory agency in any state (including Florida) for any offense that would constitute a violation of Chapter 499, F.S.?  
If yes, explain in detail in Section V |
| 3. | Yes | No | Has the applicant or any affiliated party (defined below) been convicted (regardless of adjudication) of any felony under a federal, state (including Florida), or local law?  
If yes, explain in detail in Section V |
| 4. | Yes | No | Has the applicant or any affiliated party (defined below) been denied a permit or license in any state (including Florida) related to an activity regulated under Chapters 456, 465, 499, or 893, F.S.?  
If yes, explain in detail in Section V |
| 5. | Yes | No | Has the applicant or any affiliated party (defined below) had any current or previous permit or license suspended or revoked which was issued by a federal, state, or local governmental agency relating to the manufacture or distribution of drugs, devices, or cosmetics?  
If yes, explain in detail in Section V |
| 6. | Yes | No | Has the applicant or any affiliated party (defined below) ever held a permit issued under Chapter 499, F.S., in a different name than the applicant's name? (If yes, provide the names in which each permit was issued and at what address).  
If yes, explain in detail in Section V |

The term “affiliated party” means: (a) a director, officer, trustee, partner, or committee member of a permittee or applicant or a subsidiary or service corporation of the permittee or applicant; (b) a person who, directly or indirectly, manages, controls, or oversees the operation of a permittee or applicant, regardless of whether such person is a partner, shareholder, manager, member, officer, director, independent contractor, or employee of the permittee or applicant; (c) a person who has filed or is required to file a personal information statement pursuant to s. 499.012(9) or is required to be identified in an application for a permit or to renew a permit pursuant to s. 499.012(9); or (d) the five largest natural shareholders that own at least 5 percent of the permittee or applicant.

If you answered “YES” to any questions in Section IV, you must provide detailed explanations in Section V, including requirements for submitting supporting legal documents. If needed, explain on separate sheet(s).

### Section V – Explanation(s) for “Yes” response(s) to background question(s) in Section IV

**EXPLANATION**

---

DBPR-DDC-205 - Application for Permit as an Over-The-Counter Drug Manufacturer  
Incorporated by rules: 61N-2.013, F.A.C.  
Eff. Date: April 2016  
Page 7 of 10
### Section VI - Other Permits or Licenses

**PERMITS OR LICENSES**

<table>
<thead>
<tr>
<th>Permit/License Name</th>
<th>Permit/License Type</th>
<th>Permit/License Number</th>
</tr>
</thead>
</table>

1. Are there any other permits or licenses issued by any agency of the State of Florida that authorize the purchase or possession of prescription drugs at the applicant’s establishment or address? (If no, please check this box [ ] and write "N/A" in the lines below).

   - Yes [ ]
   - No [ ]

### Section VII - Over-The-Counter Drug Manufacturing Activity

**MANUFACTURING ACTIVITIES**

Identify the types of products the applicant will manufacture or distribute under this permit.

- Solid Dose
- Liquids (Oral)
- Veterinary
- Topical
- Relabel
- Ophthalmic
- Repackage – From Bulk
- Repackage – From Stock
- Other-Explain

Identify type of operation:

- Contract Manufacturer [ ]
- Own Label Manufacturer [ ]
- Limited Manufacturing Operations (Sterilizing, Encapsulating, etc.) [ ]
Provide your Federal Food and Drug Administration (FDA) establishment registration number.

☐ FDA Establishment Registration Number: ____________________________

or.

☐ No FDA Establishment Number

1. Are products to be distributed under this permit intended for export?  □ Yes  □ No

2. Will all required records be stored and maintained at applicant’s physical address? (If no, provide the address of the establishments where all required records will be stored and maintained under question #2a.)  □ Yes  □ No

2a. Physical address where required records will be stored:

   City:  ____________________________  State:  ____________________________  Zip Code (+4 optional):  ____________________________

3. Will the required records be computerized, automated or stored electronically? If yes, will you have a back-up procedure to be able to provide required records?  □ Yes  □ No

4. Is there a quarantine area at the applicant’s establishment? (If no, provide a written explanation on a separate sheet.)  □ Yes  □ No

   Explanation included?  □ Yes  □ No  □ N/A

5. Is the applicant’s establishment equipped with adequate climate controls (including refrigerated and freezing storage if appropriate for the applicant’s distributed products) to ensure safe storage?  □ Yes  □ No

6. Are you submitting a product registration application and labels of your products with this application? (If no, explain on a separate sheet providing accurate details).

   Note: You CAN NOT SELL a product that you manufacture at the establishment until that product has been registered with the department. Selling a product before it is registered with the division is the basis for application permit denial and enforcement action by the division.

   Explanation included?  □ Yes  □ No  □ N/A

7. Do you have labels of your products ready for inspection?  □ Yes  □ No

8. Does the applicant understand that the applicant must comply with all Federal and State “Current Good Manufacturing Practices”?  □ Yes  □ No

9. Does the applicant start with a prescription drug to make any of its OTC drugs? (If yes, a Prescription Drug Manufacturer permit is required.)  □ Yes  □ No

10. Does the applicant have written policies and procedures to include: storage, inventory, distribution/disposition, record maintenance/retrieval/retention, recalls, withdrawals, and natural disasters/declared emergencies?

    (If no, provide written explanation for lack of specific policy or procedure identified above).

    Explanation attached?  □ Yes  □ No  □ N/A

    (If yes, provide a copy of each policy and procedure. Label each policy and procedure specifically identifying the subject matter in the list above that is covered by the policy or procedure. For example, the policy or procedure for receipt, security, storage, inventory could be labeled or identified as “Policy and/or Procedure for receipt, security, storage, inventory” or in another manner similar to this example.

    Policies attached?  □ Yes  □ No  □ N/A

    Policies labeled?  □ Yes  □ No  □ N/A
11. Does the applicant understand that the applicant may not possess or purchase prescription drugs? □ Yes □ No

12. Provide the date the establishment will be ready and available for inspection. This is the earliest date the application may be deemed complete.

_/_/20_

Section VIII – Affidavit

<table>
<thead>
<tr>
<th>AFFIDAVIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pursuant to s. 559.79, F.S., each application for a license or renewal of a license issued by the Department of Business and Professional Regulation shall be signed under oath or affirmation by the applicant, or owner or chief executive of the applicant without the need for witnesses unless otherwise required by law.</td>
</tr>
<tr>
<td>Pursuant to s. 559.791, F.S., any license issued by the Department of Business and Professional Regulation which is issued or renewed in response to an application upon which the person signing under oath or affirmation has falsely sworn to a material statement, including, but not limited to, the names and addresses of the owners or managers of the licensee or applicant, shall be subject to denial of the application or suspension or revocation of the license, and the person falsely swearing shall be subject to any other penalties provided by law.</td>
</tr>
<tr>
<td>I UNDERSTAND THAT THE ISSUANCE OF A PERMIT BY THE DEPARTMENT ONLY AUTHORIZES THE APPLICANT TO CONDUCT REGULATED ACTIVITIES IN THE STATE OF FLORIDA UNDER THE NAME IN WHICH THE PERMIT IS ISSUED. IF THE PERMIT IS ISSUED IN THE NAME OF A DBA OR D/B/A THE APPLICANT MAY ONLY CONDUCT BUSINESS IN FLORIDA UNDER THE NAME OF THE DBA OR D/B/A.</td>
</tr>
<tr>
<td>I FURTHER UNDERSTAND THAT PROVIDING ADDITIONAL DBA OR D/B/A NAMES TO THE DEPARTMENT AS PART OF THE APPLICATION PROCESS IS NOT, UPON LICENSURE, AN AUTHORIZATION TO CONDUCT BUSINESS IN FLORIDA UNDER THE NAME OF THOSE ADDITIONAL DBA'S OR D/B/A’S.</td>
</tr>
<tr>
<td>I certify that I am empowered to execute this application as required by s. 559.79, F.S. I understand that my signature on this application has the same legal effect as if made under oath. To the best of my knowledge, all information contained on this application is true and correct. I understand the falsification of any information on this application may result in administrative action, including a fine, suspension, or revocation of the license.</td>
</tr>
</tbody>
</table>

| Signature of Applicant, Owner or Chief Executive: | Date: |
| Print Name: | Title: |

Mail completed application to:

Department of Business and Professional Regulation
1940 North Monroe Street
Tallahassee, FL 32399
61N-2.014 Application for Prescription Drug Manufacturer Permit

A prescription drug manufacturer permit is required for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state. A person located in this state engaging in activity for which a prescription drug manufacturer permit is required, must file an application on form number DBPR-DDC-201, Application for Permit as a Prescription Drug Manufacturer, effective April 2016, adopted and incorporated herein by reference and comply with all the requirements for permitting in Chapter 499, F.S. and Rule 61N, F.A.C. This form is available upon request from the Division of Drugs, Devices and Cosmetics at 1940 N. Monroe Street, Tallahassee, Florida 32399, (850)717-1800, or at http://www.flrules.org/Gateway/reference.asp?No=Ref-06913

Rulemaking Authority 499.012(3) FS. Law Implemented 499.01, 499.012, 499.0121, 499.015, 499.04, 499.041 FS. History–New.
APPLICATION CHECKLIST – IMPORTANT – Submit all items on the checklist below with your application to ensure faster processing.

<table>
<thead>
<tr>
<th>APPLICATION</th>
<th>APPLICATION REQUIREMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application for Permit as a Prescription Drug Manufacturer</td>
<td>□ Fee of $1,650.00, which includes $1,500.00 biennial application fee and $150 initial application/on-site inspection fee. If establishment is applying for multiple manufacturing permits in the applicant’s name and at applicant’s address, you are only required to pay for the permit with the highest fee.</td>
</tr>
<tr>
<td></td>
<td>□ Make cashier’s check or money order payable to the Florida Department of Business and Professional Regulation.</td>
</tr>
<tr>
<td></td>
<td>□ If you answer “Yes” to any question in Section IV, be sure to provide a detailed explanation along with any relevant documentation.</td>
</tr>
<tr>
<td></td>
<td>□ Sign and date the Affidavit section of the application.</td>
</tr>
<tr>
<td></td>
<td>Mail completed application to: Department of Business and Professional Regulation 1940 North Monroe Street Tallahassee, FL 32399</td>
</tr>
</tbody>
</table>

PLEASE NOTE: Telephone, email, and fax contact information is used to quickly resolve questions with applications. If such information is not provided, questions regarding applications will be mailed to the application contact’s mailing address and may take longer to resolve.
Section I – Application Type

<table>
<thead>
<tr>
<th>CHECK ONE OF THE APPLICATION TYPES</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ New Application [3320/1020]</td>
</tr>
<tr>
<td>□ New Application due to change in ownership. If checked, provide legal documentation for the change of ownership (i.e. Bill of Sale, stock transfer, merger). [3320/1020]</td>
</tr>
<tr>
<td>Current Permit Number:</td>
</tr>
</tbody>
</table>

Section II – Applicant Information

<table>
<thead>
<tr>
<th>TAXPAYER IDENTIFICATION NUMBER OR FEDERAL EMPLOYER IDENTIFICATION NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>This is a unique nine-digit number assigned by the Internal Revenue Service (IRS) to business entities operating in the United States for the purposes of identification. When the number is used for identification rather than employment tax reporting, it is usually referred to as a Taxpayer Identification Number (TIN), and when used for the purposes of reporting employment taxes, it is usually referred to as the Federal Employer Identification Number (FEIN).</td>
</tr>
<tr>
<td>Applicant’s TIN/FEIN:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FULL LEGAL NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>The “full legal name” is the complete name of the business entity that will be operating the establishment. This is generally the name that is on the documents that establish the existence or formation of the business entity. For example, a corporation’s full legal name would normally be the name that is found in the corporation’s articles of incorporation.</td>
</tr>
<tr>
<td>Applicant’s Full Legal Name:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FICTITIOUS, TRADE, OR BUSINESS NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>If the applicant intends to operate the permitted establishment under a name that is different from the Applicant’s Full Legal Name listed above — e.g. fictitious, trade, or business name — (also commonly referred to as a “dba”, “d/b/a”, or “doing business as” name — this name must be registered with the Florida Department of State, Division of Corporations. This is the name that will appear on the permit issued to the applicant by the department and must be the name that the applicant uses on operational documents for permitted activities.</td>
</tr>
<tr>
<td>□ The applicant WILL NOT operate the permitted establishment under a name that is different from the Applicant’s Full Legal Name listed above.</td>
</tr>
<tr>
<td>□ The applicant WILL operate the permitted establishment under the following fictitious, trade, or business name:</td>
</tr>
</tbody>
</table>

The fictitious, trade, or business name listed directly above, is registered with the Florida Department of State, Division of Corporations and the applicant has been issued the following registration number:
<table>
<thead>
<tr>
<th><strong>APPLICANT MAILING ADDRESS</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Street Address or P.O. Box:</td>
</tr>
<tr>
<td></td>
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<tr>
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<tr>
<td><strong>City:</strong></td>
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<tr>
<td><strong>State:</strong></td>
</tr>
<tr>
<td><strong>Zip Code (+4 optional):</strong></td>
</tr>
</tbody>
</table>

**PHYSICAL ADDRESS OF ESTABLISHMENT TO BE PERMITTED**
*(only if different from mailing address) Check □ if not applicable*

<table>
<thead>
<tr>
<th><strong>Street Address:</strong></th>
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<tr>
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<tr>
<td><strong>State:</strong></td>
</tr>
<tr>
<td><strong>Zip Code (+4 optional):</strong></td>
</tr>
</tbody>
</table>

| **County (if located in Florida):** |
| **Country:** |

| **E-Mail Address (Optional):** |
| **Phone Number:** |
| **Fax Number:** |

**APPLICATION CONTACT**
The application contact is the person that the department will contact if there are questions regarding the responses provided on, or the documentation submitted with, the application. The application contact is also the person that will receive all official communication from the department regarding the application.

| **Last/Surname:** |
| **First:** |
| **Middle:** |
| **Suffix:** |

| **Address:** |
|             |

| **City:** |
| **State:** |
| **Zip Code (+4 optional):** |

| **Telephone Number:** |
| **Fax Number:** |

| **E-Mail Address:** |

**EMERGENCY CONTACT INFORMATION**
The emergency contact is the person that the department will contact in the case of an emergency. During an emergency, the department will contact this person at times outside of the regular business hours listed below. The contact information provided should be sufficient for the department to actually reach and communicate with the person listed in the event of an emergency.

| **Last/Surname:** |
| **First:** |
| **Middle:** |
| **Suffix:** |

| **Position/Title:** |
|                    |

| **Street Address:** |
|                     |

| **City:** |
| **State:** |
| **Zip Code (+4 optional):** |

| **Home Phone Number:** |
| **E-Mail Address:** |
**Section III - Ownership Information**

<table>
<thead>
<tr>
<th>TYPE OF OWNERSHIP</th>
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<tbody>
<tr>
<td>□ Publicly Held Corporation</td>
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<tr>
<td>□ Closely Held Corporation</td>
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<tr>
<td>□ Limited Liability Company</td>
</tr>
<tr>
<td>□ Charitable Organization—501(c)(3)</td>
</tr>
<tr>
<td>□ Sole Proprietorship</td>
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<tr>
<td>□ Government</td>
</tr>
<tr>
<td>□ Partnership – General</td>
</tr>
<tr>
<td>□ Professional Corporation or Association</td>
</tr>
<tr>
<td>□ Professional Limited Liability Company</td>
</tr>
<tr>
<td>□ Partnership – Other, Including Limited Liability Partnership and Limited Partnership</td>
</tr>
<tr>
<td>Other: ___________________________</td>
</tr>
</tbody>
</table>

List the state of incorporation or state of organization (except Partnership – General or Sole Proprietorship). Business entities organized under non-U.S. laws list the country of organization.

□ N/A (Partnership – General or Sole Proprietorship)

State:

Name:

Address:

City: ___________ State: ___________ Zip Code (+4 Optional): ___________

List the name, position/title, social security number, date of birth and address of each owner, partner, member, manager, officer, director, chief executive, or other person who directly or indirectly controls the operation of the business entity, as applicable. For example, corporations would list officers and directors, limited liability companies would list members and managers, etc.

<table>
<thead>
<tr>
<th>1. Name &amp; Title:</th>
<th>Social Security #:</th>
<th>Date of Birth:</th>
<th>% of Ownership:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street Address:</td>
<td>City:</td>
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<td>Zip Code:</td>
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<td>2. Name &amp; Title:</td>
<td>Social Security #:</td>
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<td>% of Ownership:</td>
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List the name, social security number, date of birth and address of each person who owns 10 percent or more of the outstanding stock or equity interest in the business entity.

<table>
<thead>
<tr>
<th>Name:</th>
<th>Social Security #:</th>
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<th>% of Ownership:</th>
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</table>

List all trade or business names used by the applicant. Use additional sheet(s) if necessary. If the applicant does not use other trade or business names check this box [ ] and write N/A on the lines below.

<table>
<thead>
<tr>
<th>Is the applicant a subsidiary of another company? (If yes, provide a listing of all parent companies with percentages of ownership, using additional sheet(s) if necessary).</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

Note: A permit issued pursuant to this application is only valid for the applicant, and the applicant’s name and address. (If no, please check this box [ ] and write “N/A” in the lines below).

<table>
<thead>
<tr>
<th>Parent Company Name</th>
<th>% of Ownership</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

DBPR-DDC-201 - Application for Permit as a Prescription Drug Manufacturer
Incorporated by rules: 81N-2.014, F.A.C.
Eff. Date: April 2016
Page 6 of 13
Is diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care services provided at the address of the establishment that is the subject of this permit application? If so, please list the name of the company/companies providing such services below. (Use additional sheet(s) if necessary.)

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

Section IV – Background Questions

<table>
<thead>
<tr>
<th>BACKGROUND QUESTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Has the applicant or any “affiliated party” (defined below) been found guilty of (regardless of adjudication), or pled nolo contendere to, in any jurisdiction, a violation of law that directly relates to a drug, device, or cosmetic?</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>If yes, explain in detail in Section V</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>2. Has the applicant or any affiliated party (defined below) been fined or disciplined by a regulatory agency in any state (including Florida) for any offense that would constitute a violation of Chapter 499, F.S.?</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>If yes, explain in detail in Section V</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>3. Has the applicant or any affiliated party (defined below) been convicted (regardless of adjudication) of any felony under a federal, state (including Florida), or local law?</td>
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<tr>
<td>Yes</td>
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<tr>
<td>If yes, explain in detail in Section V</td>
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<td>4. Has the applicant or any affiliated party (defined below) been denied a permit or license in any state (including Florida) related to an activity regulated under Chapters 456, 465, 499, or 893, F.S.?</td>
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<tr>
<td>Yes</td>
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<td>If yes, explain in detail in Section V</td>
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<td>5. Has the applicant or any affiliated party (defined below) had any current or previous permit or license suspended or revoked which was issued by a federal, state, or local governmental agency relating to the manufacture or distribution of drugs, devices, or cosmetics?</td>
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<td>Yes</td>
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<td>If yes, explain in detail in Section V</td>
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<td>6. Has the applicant or any affiliated party (defined below) ever held a permit issued under Chapter 499, F.S., in a different name than the applicant’s name? (If yes, provide the names in which each permit was issued and at what address.)</td>
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<tr>
<td>Yes</td>
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<td>If yes, explain in detail in Section V</td>
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The term “affiliated party” means: (a) a director, officer, trustee, partner, or committee member of a permittee or applicant or a subsidiary or service corporation of the permittee or applicant; (b) a person who, directly or indirectly, manages, controls, or oversees the operation of a permittee or applicant, regardless of whether such person is a partner, shareholder, manager, member, officer, director, independent contractor, or employee of the permittee or applicant; (c) a person who has filed or is required to file a personal information statement pursuant to s. 499.012(9) or is required to be identified in an application for a permit or to renew a permit pursuant to s. 499.012(8); or (d) the five largest natural shareholders that own at least 5 percent of the permittee or applicant.

If you answered “YES” to any questions in Section IV, you must provide detailed explanations in Section V, including requirements for submitting supporting legal documents. If needed, explain on separate sheet(s).
### Section V – Explanation(s) for “Yes” response(s) to background question(s)

<table>
<thead>
<tr>
<th>EXPLANATION</th>
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### Section VI – Other Permits or Licenses

#### PERMITS OR LICENSES

1. Are there any other permits or licenses issued by any agency of the State of Florida that authorize the purchase or possession of prescription drugs at the applicant's establishment or address? (If no, please check this box and write "N/A" in the lines below).

<table>
<thead>
<tr>
<th>Permit/License Name</th>
<th>Permit/License Type</th>
<th>Permit/License Number</th>
<th>Yes</th>
<th>No</th>
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2. Is the applicant licensed in any other state as a manufacturer, repackager, or wholesaler of prescription drugs? (If yes, list all states where licensed, including the license numbers and expiration date. Use separate sheet of paper if needed).

<table>
<thead>
<tr>
<th>State</th>
<th>Permit/License Type</th>
<th>Permit/License Number</th>
<th>Expiration Date</th>
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3. Does or will the applicant ship or otherwise physically transfer prescription drugs in or from Florida? (If no, provide name, address, and Florida permit number of the shipper/transferor).

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>Florida Permit Number</th>
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3a. 

Section VII – Prescription Drug Manufacturing Activity

MANUFACTURING ACTIVITIES

Generally identify the applicant's intended customers, the persons and entities that will purchase or receive products from the applicant after permit issuance.

☐ Manufacturers  ☐ Wholesalers  ☐ Pharmacies
☐ Hospitals  ☐ Practitioners  ☐ Clinics
☐ Veterinarians  ☐ Other (explain) ________________

Identify the types of products the applicant will manufacture or distribute under this permit.

☐ Human Prescription Drugs  ☐ Veterinary Prescription Drugs
☐ Solid Dose  ☐ Repackage – From Bulk
☐ Liquids (Oral)  ☐ Repackage – From Stock
☐ Injectables  ☐ Refrigerated (Human, Veterinary, API or Otherwise)
☐ Topical  ☐ Frozen (Human, Veterinary, API or Otherwise)
☐ Dental  ☐ Compressed Medical Gases
☐ Ophthalmic

☐ Active Pharmaceutical Ingredients (If yes, check the applicable box(es) for your customers):
   ☐ Manufacturers  ☐ Pharmacies for Compounding  ☐ Other explain ________________

Controlled Substances: Provide your DEA Number: ________________ or check ☐ No DEA Number

☐ Check Schedules:  ☐ Sch II  ☐ Sch III  ☐ Sch IV  ☐ Sch V

Identify type of operation.

☐ Contract Manufacturer  ☐ Own Label Manufacturer  ☐ Limited Manufacturing Operations (Sterilizing, Encapsulating, etc.)

Provide your Federal Food and Drug Administration (FDA) establishment registration number.

☐ FDA Establishment Registration Number: ________________________

or

☐ No FDA Establishment Number.
1. Are products distributed to be under this permit intended for export? (Note: A permit may be required for freight forwarders handling products in Florida.)

2. Do you manufacture a prescription drug as a finished product? (If no, explain on a separate sheet providing accurate details.)

3. Are you submitting a product registration application and labels of your products with this application? (If no, explain on a separate sheet providing accurate details.)

**Note:** You **CANNOT SELL** a product that you manufacture at the establishment until that product has been registered with the department. Selling a product before it is registered with the division is the basis for application permit denial and enforcement action by the division.

Explanation included? □ Yes □ No □ N/A

4. Do you intend to manufacture or distribute prescription drug samples? (If yes, a Complimentary Drug Distributor permit is required.)

5. Will all required records be stored and maintained at applicant's physical address? (If no, provide the address of the establishments where all required records will be stored and maintained under question #5a.)

5a. Physical address where required records will be stored:
Street Address:

City: ______________________ State: ______ Zip Code (+4 optional): ______

6. Will the required records be computerized, automated or stored electronically? □ Yes □ No

if yes, will you have a back-up procedure to be able to provide required records?

7. Is the applicant's establishment equipped with an alarm system to detect entry after hours and a security system protecting against theft and diversion?

(If yes, provide a written description of the alarm and security systems, that include: the type of system and how the system is monitored)

Description included? □ Yes □ No □ N/A

(If no, provide a written explanation of why the establishment is not equipped with an alarm or security system.)

Explanation included? □ Yes □ No □ N/A

8. Is there a quarantine area at the applicant's establishment? (If no, provide a written explanation on a separate sheet.)

Explanation included? □ Yes □ No □ N/A

9. Will you distribute prescription drugs, including any active pharmaceutical ingredient (API), used or intended for use in the manufacture of a prescription drug from the establishment? (For assistance in determining the definition of "distribute" see Section 499.003, Florida Statutes.)

□ Yes □ No

10. Is the applicant's establishment equipped with adequate climate controls (including refrigerated and freezing storage if appropriate for the applicant's distributed products) to ensure safe storage?

□ Yes □ No
11. Does the applicant have written policies and procedures to include: the receipt, security, storage, inventory, distribution/disposition of prescription drugs; distributing oldest approved stock first (FIFO); identifying, recording and reporting prescription drug losses and thefts; maintenance, retrieval and retention of required records; prescription drug recalls and withdrawals; natural disasters and other emergencies; segregation and destruction of outdated products; temperature and humidity monitoring?

(If no, provide written explanation for lack of specific policy or procedure identified above).

   Explanation attached?  □ Yes  □ No  □ N/A

(If yes, provide a copy of each policy and procedure. Label each policy and procedure specifically identifying the subject matter in the list above that is covered by the policy or procedure. For example, the policy or procedure for receipt, security, storage, inventory could be labeled or identified as “Policy and/or Procedure for receipt, security, storage, inventory” or in another manner similar to this example.

   Policies attached?  □ Yes  □ No  □ N/A
   Policies labeled?  □ Yes  □ No  □ N/A

12. Provide the date the establishment will be ready and available for inspection. This is the earliest date the applicant may be deemed complete.

   ___/___/20___

Section VIII– Qualify as a Manufacturer
### QUALIFYING AS A MANUFACTURER

(Check all that apply)

- For the purpose of the questions below, the term "affiliate" means a business entity that has a relationship with another business entity in which, directly or indirectly:
  a. The business entity controls, or has the power to control, the other business entity; or
  b. Third party controls, or has the power to control, both business entities.

- FDA approvals must be in the name of the applicant as listed on this application. If the FDA approval is not in the same name as the applicant as listed on this application, you may not qualify as a manufacturer.

1. Does the applicant hold New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), a Biologics License Application (BLA), or a New Animal Drug Application (NADA) approved under the federal act? If yes, provide a list of all approved applications and licenses by number on a separate sheet, and provide copies of no more than 5 FDA approval letters.
   - List of applications/licenses attached? [ ] Yes [ ] No
   - Copies of approval letters attached? [ ] Yes [ ] No

2. Does the applicant hold a license issued under s. 351 of the Public Health Service Act, 42 U.S.C. s. 262 for a drug or biologic? If yes, provide a list of the approved licenses by number on a separate sheet, and provide a copy of no more than 5 FDA licenses for drugs or biologics.
   - List of licenses attached? [ ] Yes [ ] No
   - Copies of licenses attached? [ ] Yes [ ] No

3. Does the applicant “manufacture” drugs or biologics that are not the subject of an approved FDA application or license? If yes, please provide:
   a. All labeling associated with the drug or biologics manufactured;
   b. A written description of the applicant’s intent with respect to the drug or biologic, i.e., clinical trial, distribution or commercial sale, etc.; and
   c. Documentation that the drug or biologic can be legally placed into interstate commerce as per FDA regulations, for example, a copy of section(s) of the Code of Federal Regulations (CFR) denoting the product Drug Efficacy Study Implementation (DESI) designation or a copy of section(s) of the CFR denoting the product remains pending final DESI review, or a copy and summary of material(s) and authoritative literature reviewed during the applicant’s investigation supporting that the product has not yet been reviewed in the DESI process.
   - Labeling attached? [ ] Yes [ ] No
   - Description of intent attached? [ ] Yes [ ] No
   - Supportive documentation attached? [ ] Yes [ ] No

4. Is the applicant an affiliate of a person described in 1, 2, or 3 above that receives drugs or biologics directly from a person described in 1, 2, or 3 above or another affiliate of such person? If yes, please provide the following:
   a. If the applicant and the affiliate fall under the same business / organizational structure, i.e., one company is a parent, subsidiary, or sister / brother company of the other, provide written documentation describing the relationships between the companies, including, where applicable, the percentages of ownership that each company, e.g. an organizational chart; and
   b. The name, address, and Florida manufacturer permit, unless exempt from permitting, of the affiliate from whom the applicant receives drugs or biologics.
   - Relationship documents attached? [ ] Yes [ ] No
   - Documents are considered trade secret? [ ] Yes [ ] No
   - List of affiliates attached? [ ] Yes [ ] No
   - List of affiliated considered trade secret? [ ] Yes [ ] No
Section IX – Affidavit

AFFIDAVIT

Pursuant to s. 559.79, F.S., each application for a license or renewal of a license issued by the Department of Business and Professional Regulation shall be signed under oath or affirmation by the applicant, or owner or chief executive of the applicant without the need for witnesses unless otherwise required by law.

Pursuant to s. 559.791, F.S., any license issued by the Department of Business and Professional Regulation which is issued or renewed in response to an application upon which the person signing under oath or affirmation has falsely sworn to a material statement, including, but not limited to, the names and addresses of the owners or managers of the licensee or applicant, shall be subject to denial of the application or suspension or revocation of the license, and the person falsely swearing shall be subject to any other penalties provided by law.

I UNDERSTAND THAT THE ISSUANCE OF A PERMIT BY THE DEPARTMENT ONLY AUTHORIZES THE APPLICANT TO CONDUCT REGULATED ACTIVITIES IN THE STATE OF FLORIDA UNDER THE NAME IN WHICH THE PERMIT IS ISSUED. IF THE PERMIT IS ISSUED IN THE NAME OF A DBA OR D/B/A THE APPLICANT MAY ONLY CONDUCT BUSINESS IN FLORIDA IN THE NAME OF THE DBA OR D/B/A.

I FURTHER UNDERSTAND THAT PROVIDING ADDITIONAL DBA OR D/B/A NAMES TO THE DEPARTMENT AS PART OF THE APPLICATION PROCESS IS NOT, UPON LICENSURE, AN AUTHORIZATION TO CONDUCT BUSINESS IN FLORIDA UNDER THE NAME OF THOSE ADDITIONAL DBA’S OR D/B/A’S.

I certify that I am empowered to execute this application as required by s. 559.79, F.S. I understand that my signature on this application has the same legal effect as if made under oath. To the best of my knowledge, all information contained on this application is true and correct. I understand the falsification of any information on this application may result in administrative action, including a fine, suspension, or revocation of the license.

Signature of Applicant, Owner or Chief Executive: Date:

Print Name: Title:

Mail completed application to:
Department of Business and Professional Regulation
1940 North Monroe Street
Tallahassee, FL 32399

DBPR-DDC-201 - Application for Permit as a Prescription Drug Manufacturer
Incorporated by rules: 61N-2.014, F.A.C.
Eff. Date: April 2016
Page 13 of 13
Notice of Development of Rulemaking

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
Drugs, Devices and Cosmetics
RULE NO.: RULE TITLE:
61N-1.001 General Regulations; Definitions
PURPOSE AND EFFECT: To define terms that are used in Chapter 499, F.S. and Rule 61N, F.A.C. and to adopt and incorporate the division’s permitting application forms into rule.
SUBJECT AREA TO BE ADDRESSED: The proposed rule development: sets the limit on the amount of prescription drugs that may be distributed by a retail pharmacy before that pharmacy is required to be permitted by the division; establishes the criteria for determining when distributions between commonly owned, End-Stage Renal Dialysis pharmacies is such that it requires a license from the department; and revises the application forms that permit applicants for virtual prescription drug manufacturers and repackers must submit.
RULEMAKING AUTHORITY: 499.01, 499.012, 499.0121, 499.04, 499.041 FS.
LAW IMPLEMENTED: 499.01, 499.012, 499.0121, 499.015, 499.04, 499.041 FS.
IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE NOTICED IN THE NEXT AVAILABLE FLORIDA ADMINISTRATIVE REGISTER.
THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT, IF AVAILABLE, IS: Dinah Greene, Division of Drugs, Devices and Cosmetics, Department of Business and Professional Regulation, 1940 N. Monroe St., Suite 26A, Tallahassee, FL 32399-1047, Dinah.Greene@myfloridalicense.com, (850)488-1802
THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS NOT AVAILABLE.
61N-1.001 General Regulations; Definitions.

(1) A word or phrase defined in the federal Food, Drug, and Cosmetic Act as defined in paragraph 499.002(1)(b), F.S., shall have the same meaning as in those provisions unless specifically defined otherwise in Chapter 499, F.S. or Rule Chapter 61N-1, F.A.C.

(2) In addition to definitions contained in Sections 499.003, 499.028(1), 499.029(3), and 499.61, F.S., the following definitions apply to Chapter 499, F.S. and to Rule Chapters 61N-1 and 61N-2, F.A.C.:

(a) “Administer” or “administration” – means the direct application or introduction of a single dose of drugs by a legally authorized person to or into the body of an individual human or animal patient whether by injection, inhalation, ingestion or any other means.


(c) through (g) renumbered (b) through (f) No change.

(h) "Directly from the manufacturer"—means, for purposes other than set forth in Section 499.003(46), F.S., the manufacturer of the specific unit of the prescription drug invoiced and sent that specific unit of the prescription drug directly to the purchasing wholesale distributor, or shipped the specific unit of the prescription drug directly to an authorized recipient.

(i) through (n) renumbered (g) through (l) No change.

(m) “Minimal quantities” for the purpose of distribution of prescription drugs by a licensed retail pharmacy to a license practitioner for office use in compliance with chapter 465, F.S., pursuant to section 499.003(48)(m), F.S., means the total annual dollar volume of prescription drugs sold does not exceed five percent of the total dollar volume of that pharmacy’s annual prescription drug sales.

(n) “Limited quantities” for the purpose of prescription drugs or active pharmaceutical ingredients obtained in “limited quantities” for research and development (“R&D”) purposes pursuant to Sections 499.01(3) and (4)(b), F.S., requires that the entity must identify the R&D requirements, the acquisition schedule and the use of each drug acquired relative to anticipated and ongoing R&D activities.

(o) “Pedigree”—means a document that satisfies the requirements of Section 499.003(37), F.S., as applicable, and the applicable rule requirements of subsection 61N-1.012(3), F.A.C., and any forms adopted therein.

(p) through (v) renumbered (n) through (t) No change.

(u) “Regular and systematic supplying of a drug” for the purpose of distributions of prescription drugs between licensed pharmacies operating in end-stage renal dialysis clinics pursuant to s. 499.01(2)(h)5., F.S., means the distribution of that prescription drug where the receiving pharmacy:

1. Has failed to establish a written policy and procedure for forecasting the pharmacy’s prescription drug inventory needs based on the pharmacy’s historical prescription drug dispensing records;

2. Has failed to establish and maintain an inventory of prescription drugs based on historical prescription drug dispensing records; and

3. Has implemented a business practice where a prescription drug shortage is resolved primarily by obtaining prescription drugs from another pharmacy under common ownership.

(w) through (ii) renumbered (v) through (th) No change.
Notice of Development of Rulemaking

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
Drugs, Devices and Cosmetics
RULE NO.: RULE TITLE:
61N-2.0111 Application for Nonresident Prescription Drug Manufacturer- Virtual Permit
PURPOSE AND EFFECT: To define terms that are used in Chapter 499, F.S. and Rule 61N, F.A.C. and to adopt and incorporate the division's permitting application forms into rule.
SUBJECT AREA TO BE ADDRESSED: The proposed rule development: sets the limit on the amount of prescription drugs that may be distributed by a retail pharmacy before that pharmacy is required to be permitted by the division; establishes the criteria for determining when distributions between commonly owned, End-Stage Renal Dialysis pharmacies is such that it requires a license from the department; and revises the application forms that permit applicants for virtual prescription drug manufacturers and repackers must submit.
RULEMAKING AUTHORITY: 499.01, 499.012, 499.0121, 499.04, 499.041 FS.
LAW IMPLEMENTED: 499.01, 499.012, 499.0121, 499.015, 499.04, 499.041 FS.
IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE NOTICED IN THE NEXT AVAILABLE FLORIDA ADMINISTRATIVE REGISTER.
THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT, IF AVAILABLE, IS: Dinah Greene, Division of Drugs, Devices and Cosmetics, Department of Business and Professional Regulation, 1940 N. Monroe St., Suite 26A, Tallahassee, FL 32399-1047, Dinah.Greene@myfloridalicense.com, (850)488-1802.
THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS NOT AVAILABLE.
Notice of Development of Rulemaking

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
Drugs, Devices and Cosmetics
RULE NO.: RULE TITLE:
61N-2.0141 Application for Prescription Drug Manufacturer- Virtual Permit
PURPOSE AND EFFECT: To define terms that are used in Chapter 499, F.S. and Rule 61N, F.A.C. and to adopt and incorporate the division’s permitting application forms into rule.
SUBJECT AREA TO BE ADDRESSED: The proposed rule development: sets the limit on the amount of prescription drugs that may be distributed by a retail pharmacy before that pharmacy is required to be permitted by the division; establishes the criteria for determining when distributions between commonly owned, End-Stage Renal Dialysis pharmacies is such that it requires a license from the department; and revises the application forms that permit applicants for virtual prescription drug manufacturers and repackers must submit.
RULEMAKING AUTHORITY: 499.01, 499.012, 499.0121, 499.04, 499.041 FS.
LAW IMPLEMENTED: 499.01, 499.012, 499.0121, 499.015, 499.04, 499.041 FS.
IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE NOTICED IN THE NEXT AVAILABLE FLORIDA ADMINISTRATIVE REGISTER.
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THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS NOT AVAILABLE.
Notice of Development of Rulemaking

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
Drugs, Devices and Cosmetics
RULE NO.: RULE TITLE:
61N-2.0151 Application for Nonresident Prescription Drug Repackager Permit
PURPOSE AND EFFECT: To define terms that are used in Chapter 499, F.S. and Rule 61N, F.A.C. and to adopt and incorporate the division's permitting application forms into rule.
SUBJECT AREA TO BE ADDRESSED: The proposed rule development: sets the limit on the amount of prescription drugs that may be distributed by a retail pharmacy before that pharmacy is required to be permitted by the division; establishes the criteria for determining when distributions between commonly owned, End-Stage Renal Dialysis pharmacies is such that it requires a license from the department; and revises the application forms that permit applicants for virtual prescription drug manufacturers and repackers must submit.
RULEMAKING AUTHORITY: 499.01, 499.012, 499.0121, 499.04, 499.041 FS.
LAW IMPLEMENTED: 499.01, 499.012, 499.0121, 499.015, 499.04, 499.041 FS.
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THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS NOT AVAILABLE.