

**STATE OF FLORIDA  
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION**

<b>FILED</b>	
Department of Business and Professional Regulation Deputy Agency Clerk	
CLERK	Brandon Nichols
Date	<b>12/29/2016</b>
File #	<b>2016-09957</b>

**In Re: Petition for Declaratory  
Statement,**

**DS 2016-079**

**National Association of Chain Drug  
Stores,  
Petitioner.**

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**FINAL ORDER DENYING PETITION FOR DECLARATORY STATEMENT**

The Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics (“Department” or “Division”), hereby denies the Petition for Declaratory Statement in accordance with Section 120.565, Florida Statutes.

**PRELIMINARY STATEMENT**

On October 17, 2016, the Division of Drugs, Devices, and Cosmetics received a Petition for Declaratory Statement filed by counsel for the National Association of Chain Drug Stores (“NACDS” or “Petitioner”). The Petitioner seeks a declaratory statement as to whether NACDS members operating in Florida: (a) are subject to felony criminal liability and penalties in instances when the transaction history, transaction information, or transaction statement (3Ts) they may receive and maintain from prescription drug manufacturers and prescription drug wholesale distributors does not completely nor accurately reflect what is actually received by the pharmacy but is otherwise in compliance with federal law and (b) are required to maintain records beyond those mandated by federal law, for the purpose of product tracking and tracing.

Notice of the Petition was published in the October 27, 2016, edition of the Florida Administrative Register, Volume 42, Number 210. The petition is attached as Exhibit A.

### **FINDINGS OF FACT**

The Department takes no position with regard to the validity of the facts. NACDS states the facts as follows:

1. NACDS is a 501(c)(6) association headquartered at 1776 Wilson Boulevard, Suite 200, Arlington, Virginia 22209, which represents traditional drug stores and supermarkets and mass merchants with pharmacies.

2. NACDS' chain member companies include regional chains, with a minimum of four stores, and national companies.

3. NACDS has 15 chain members in Florida who operate nearly 2900 pharmacies.

4. NACDS members purchase their prescription drugs either directly from the manufacturer or, in most instances, from wholesalers. When the pharmacy receives the purchased drugs, it also receives the 3Ts—transaction history, transaction information, and transaction statement, that is to accompany those drugs by law.

5. There may be instances in which the 3Ts do not correspond exactly to the product received. For example, if there is a shortage, the number of drugs received may be less than the number of drugs reflected in the 3Ts.

6. NACDS members are not in control of the 3Ts that they receive from the manufacturer or wholesaler. To expose pharmacies to felony violations for receiving incomplete or inaccurate 3Ts, through no fault of their own, is inappropriate and

unlawful. More specifically, to impose the obligation on NACDS members in Florida which effectively requires them to ensure the correction of 3Ts upon receipt if they are not accurate nor complete is beyond the scope of federal law. Further, it would be exceptionally burdensome from a financial and operational perspective and would likely negatively impact pharmacy inventories and delay patient access to those prescription medications.

7. Included in the 3Ts is “transactional information,” which is defined identically under Florida and federal law. *Compare* Rule 61N-1.028(27), FAC *with* 21 U.S.C. § 360eee(26). Under these identical definitions, “transactional information” includes only the following: proprietary name of the product; product strength and dosage; product National Drug Code Number; container size and number; product lot number; date of transaction and ship; and the names and addresses of the one sending and the one receiving the product.

8. Members receive the 3Ts from the manufacturer or wholesaler for the corresponding prescription drug purchase. But Members are not required to obtain other records as a part of that transaction, which would be in addition to or outside of the 3Ts. To impose that additional record keeping obligation on Members would result in additional administrative and record-keeping expenses and would require a re-allocation of resources and additional costs.

9. Under Florida law, pharmacies are required to obtain the 3Ts upon receipt of the prescription drugs they have purchased. 61N-1.031(1)(a), FAC. Further, the pharmacy “shall capture” the 3Ts “as necessary to investigate a suspect product” and

maintain it for six (6) years. 61N-1.031(1)(c), FAC. This parallels the federal requirement.

10. Further, Florida law, FL Stat. Ann. § 499.0051(1)(c), states as follows:

FAILURE TO MAINTAIN OR DELIVER TRANSACTION  
HISTORY TRANSACTION INFORMATION, OR TRANS-  
ACTION STATEMENT.

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(c) Any person who knowingly destroys, alters, conceals, or fails to *maintain a complete and accurate* transaction history, transaction information, or transaction statement 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. 775.803 or s. 775.084. (emphasis added) (sic)

11. Under Florida State law, a third degree felony may subject a person to up to five years in prison, see Fl. Stat. Ann. § 775.082(e) and a five thousand dollar (\$5,000) fine, see Fl. Stat. Ann. § 775.083(c). See also Fl. Stat. Ann. §§ 775.084(4)(a)(3), (b)(3), (c)(1)(iii), (listing the prison terms of up to ten (10) years for “habitual offenders.”

12. Under the federal track and trace law, the Drug Supply Chain Safety (sic) Act, 21 U.S.C. § 360eee et seq. (“DSCSA”), dispensers are not permitted to “accept ownership of a product, unless the previous owner prior to, or at the time of, the transaction, provides” the 3Ts. 21 U.S.C. §360eee-1(d)(1)(A)(i).

13. The dispenser is required to “capture” the 3Ts to the extent “necessary to investigate a suspect product, and maintain” it for at least six years. Id. § 360eee-1(d)(1)(A)(iii).

14. Failure to comply with these provisions is a prohibited act under 21 U.S.C. § 331(t) and could result in misdemeanor related penalties of up to one (1) year in

prison or up to one thousand dollars (\$1,000) in fines. See 21 U.S.C. § 333(a)(1); see also 21 U.S.C. § 331(a)(2) (increasing prison term up to three (3) years and fines up to ten thousand dollars (\$10,000) for repeat offenders).

15. Importantly, DSCSA preempts all state law as follows:

No State or political subdivision of a State may establish or continue in effect any requirements for tracing products through the distribution system (including any requirements with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, recordkeeping relating to such systems, including paper electronic pedigree systems or for tracking drugs throughout the distribution system) which are inconsistent with, more stringent than, or in addition to, any requirements applicable under section 353(e) of this title or this part (or regulations issued thereunder), or which are inconsistent with----

- (1) any waiver, exception, or exemption pursuant to section 360eee or 360eee-1 of this title; or
- (2) any restrictions specified in section 360eee- 1 of this title.

21 U.S.C. §360eee-4 (emphasis added).<sup>1</sup>

16. NACDS Members are under a significant burden to comply with the federal requirements of capturing and maintain the 3Ts under the DSCSA. While they seek to comply with these new track and trace obligations, they find benefit in the national program and standard under the DSCSA versus varying obligations under individual state requirements. Indeed, as reflected by the preemption language above, that was intent of Congress in passing the DSCSA.

17. In Florida, however, NACDS Members are at risk for increased criminal penalties for failing to comply with additional obligations regarding completeness and

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<sup>1</sup> The Department has previously recognized the preemption authority of the DSCSA. See Declaratory Statement In re: Petition for Declaratory Statement, Publix Super Markets, Inc., DS 2014-007, Filed April 15, 2014 found at <http://www.myfloridalicense.com/dbpr/ddc/documents/PublixSupermarkets.pdf>.

accuracy of the 3Ts beyond that required by federal law. *Compare* FL. Stat. Ann. § 499.0051(1)(c) *with* 21 U.S.C. §360ee-1(d)(1)(A)(iii). They also have an obligation to maintain additional information/documentation beyond the federally prescribed scope of the 3Ts.

18. The consequences of these potential additional burdens are real for NACDS Members and the patients they serve. If procedures must be developed and implemented to meet additional state requirements, this will take significant resources, including both personnel and monetary, not anticipated as part of track and trace compliance. The economic impact will be harmful. Further, once implemented, added paperwork and verification burden may have a large impact on patient access to needed medication as it could take longer for NACDS Members to incorporate the prescription drugs into pharmacy inventory. Failure to undertake these unduly burdensome steps, beyond what federal law requires, could leave an NACDS Member with state felony exposure.

19. NACDS Members need to have certainty and predictability in their obligations under track and trace laws as intended by the DSCSA, but the provisions of Florida law presented herein threaten to defeat that purpose with provisions that may operate in a manner that is “inconsistent with, more stringent than, or in addition to, any [DSCSA] requirements applicable. . .” 21 U.S.C. §360eee-4.

20. First, FL. Stat. Ann. §§ 499.0051(1)(c) imposes greater penalties, contrary to DSCSA, for failing to maintain the 3Ts, putting NACDS Members at risk for felony violations when similar violations are deemed misdemeanors under DSCSA. It also conflicts with federal law to the extent it requires different maintenance standards - -

requiring maintaining “accurate” 3Ts versus maintaining 3Ts “necessary to investigate suspect product”. Florida’s accuracy requirement imposes additional felony liability on pharmacies if they maintain inaccurate 3Ts through no fault of their own. This is not permitted under the DSCSA. In each instance where state law conflicts with federal law, that would require preemption by DSCSA. See 21 U.S.C. §360eee-4(a).

21. As for recordkeeping requirements for “business records” under §499.121(6)(b), Florida adds additional documents to those included in the transaction information of the 3Ts. See 21 U.S.C. §360eee(26); see also Rule 61N-1.028(27), FAC. This additional recordkeeping burden also is expressly preempted by DSCSA. See 21 U.S.C. §360eee-4(a).

22. NACDS Members wish to avoid the additional administrative and operational burdens described herein that exceeds the scope of their obligations under DSCSA and to avoid the risk of being subject to increased administrative or criminal proceedings (sic) violating Chapter 499 if they do not assume those burdens. Therefore, NACDS is justified in seeking this declaratory statement to clarify NACDS Members rights under the above statutes.

23. NACDS requests that the Department issue a Declaratory Statement determining that:

A. When NACDS members purchase prescription drugs from a manufacturer or wholesaler, their obligations to maintain the 3Ts received from manufacturers and wholesalers do not exceed their obligations under federal law.

B. After NACDS members purchase prescription drugs from a manufacturer or wholesaler, if they fail to maintain the 3Ts pursuant to those obligations, their liability does not exceed that applicable under federal law.

C. When NACDS members purchase prescription drugs from a manufacturer or wholesaler, they are not required to maintain “business records” related to the transaction that fall outside the scope of transactional information contained in the 3Ts, as prescribed by federal law.

### **CONCLUSIONS OF LAW**

24. The Department is the state agency charged with the regulation of drugs, devices, and cosmetics, pursuant to Chapter 499, Florida Statutes.

25. The Department has jurisdiction to enter this order pursuant to Section 120.565, Florida Statutes, and Rule 28-105.003, Florida Administrative Code.

26. Section 120.565, Florida Statutes, provides:

#### **120.565 Declaratory statement by agencies.—**

(1) Any substantially affected person may seek a declaratory statement regarding an agency’s opinion as to the applicability of a statutory provision, or of any rule or order of the agency, as it applies to the petitioner’s particular set of circumstances.

(2) The petition seeking a declaratory statement shall state with particularity the petitioner’s set of circumstances and shall specify the statutory provision, rule, or order that the petitioner believes may apply to the set of circumstances.

(3) The agency shall give notice of the filing of each petition in the next available issue of the Florida Administrative Register and transmit copies of each petition to the committee. The agency shall issue a declaratory statement or deny the petition within 90 days after the filing of the petition. The declaratory statement or denial of the petition shall be noticed in the next available issue of the Florida Administrative Weekly. Agency disposition of petitions shall be final agency action.

27. Rules 28-105.001 and 28-105.003, Florida Administrative Code, provide:

#### **28-105.001 Purpose and Use of Declaratory Statement**

A declaratory statement is a means for resolving a controversy or answering questions or doubts concerning the applicability of statutory provisions, rules, or orders over which the agency has authority. A petition for declaratory statement may be used to resolve questions or doubts as to how the statutes, rules, or orders



may apply to the petitioner's particular circumstances. A declaratory statement is not the appropriate means for determining the conduct of another person.

**28-105.003 Agency Disposition.**

The agency may hold a hearing to consider a petition for declaratory statement. If the agency is headed by a collegial body, it shall take action on a petition for declaratory statement only at a duly noticed public meeting. The agency may rely on the statements of fact set out in the petition without taking any position with regard to the validity of the facts. Within 90 days of the filing of the petition, the agency shall render a final order denying the petition or issuing a declaratory statement.

28. The Petitioner is substantially affected by the Department's statutes and rules referenced above.

29. The Petitioner makes the conclusion that the Department's statutes and rules are preempted by federal law, based on Petitioner's interpretation of the Drug Supply Chain Security Act. The Petitioner cites to a declaratory statement issued by the Department in In Re Petition for Declaratory Statement, Publix Super Markets, Inc., Petitioner (DS 2014-007 April 15, 2014), in which the Department interpreted its pedigree laws in light of changes to the federal law and concluded that the Department's pedigree laws were preempted by the enactment of the federal law.

30. Since enactment of the Drug Supply Chain Security Act, the Florida Legislature enacted changes to Sections 499.0121(6)(a), 499.0121(6)(b), 499.0121(6)(f), and 499.0051(1)(c), Florida Statutes, making it clear the requirements for business records that are required to be kept to ensure that persons distributing, packaging, shipping and receiving prescription drugs are permitted to do so. Further, the Department engaged in rulemaking to add new rules 61N-1.028, and 61N-1.031,

Florida Administrative Code. Petitioner is not asking how these statutes and rules affect petitioner in its circumstances. Rather, the Petitioner is attempting to challenge both the statutes and the rules referenced above. The Petitioner asks the Department to declare that the DSCSA pre-empts the Department's statutes and rules cited in the Petition, *in accordance with the Petitioner's interpretation of the DSCSA*. This the Department cannot do in a proceeding on a Petition for Declaratory Statement.

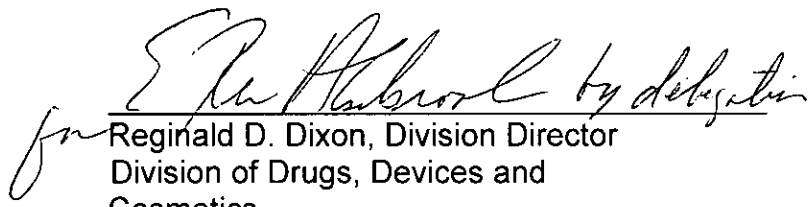
31. Based on the foregoing, the Department declines to issue a declaratory statement, and the Petition is DENIED.

Done and ordered this 28<sup>th</sup> day of December, 2016, at

Tallahassee, Leon County, Florida.

KEN LAWSON, SECRETARY  
Department of Business & Professional  
Regulation

BY:

 *Reginald D. Dixon by delegation*

Reginald D. Dixon, Division Director  
Division of Drugs, Devices and  
Cosmetics  
1940 North Monroe Street, Suite 26A  
Tallahassee, FL 32399-1047  
Telephone: (850) 717-1800  
Facsimile: (850) 414-8240


**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by Electronic mail to Mary Ellen Kleiman, Esquire, National Association of Chain Drug stores, 1776 Wilson Blvd., Suite 200, Arlington, VA 22209 (mkleiman@nacds.org), this 29<sup>th</sup> day of December, 2016.

for:   
Agency Clerk

Copies furnished to:

Reginald D. Dixon  
DDC Division Director

  
Kathryn B. Price  
DDC Chief Attorney

**NOTICE OF RIGHTS TO APPEAL**

THIS FINAL ORDER CONSTITUTES FINAL AGENCY ACTION AND MAY BE APPEALED BY ANY PARTY ADVERSELY AFFECTED PURSUANT TO SECTION 120.68, FLORIDA STATUTES, AND RULE 9.110, FLORIDA RULES OF APPELLATE PROCEDURE, BY FILING A NOTICE OF APPEAL CONFORMING TO THE REQUIREMENT OF RULE 9.110(C), FLORIDA RULES OF APPELLATE PROCEDURE, BOTH WITH THE APPROPRIATE DISTRICT COURT OF APPEAL ACCOMPANIED BY THE APPROPRIATE FILING FEE AND WITH THE AGENCY CLERK, 1940 NORTH MONROE STREET, NORTHWOOD CENTRE, TALLAHASSEE, FLORIDA 32399-2217, WITHIN THIRTY DAYS OF RENDITION OF THIS FINAL ORDER.

**BEFORE THE STATE OF FLORIDA  
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION**

<b>FILED</b>	
Department of Business and Professional Regulation Deputy Agency Clerk	
CLERK	Brandon Nichols
Date	10/17/2016
File #	

In re: National Association of Chain Drug Stores' )  
Petition for Declaratory Statement before the Florida )  
Department of Business and Professional Regulation )

Case No: **DS 2016-079**

**National Association of Chain Drug Stores' Petition for Declaratory Statement**

The National Association of Chain Drug Stores' ("NACDS") files this Petition for Declaratory Statement pursuant to Section 120.565, Florida Statutes, and Rule 28-105.002, FAC. As grounds therefore, NACDS' states:

1. NACDS is requesting that the Department of Business and Professional Regulation ("Department") declare that NACDS members operating in Florida (a) are not subject to felony criminal liability and penalties in instances when the transaction history, transaction information, or transaction statement ("3Ts") they may receive and maintain from manufacturers and wholesalers does not completely nor accurately reflect what is actually received by the pharmacy but is otherwise in compliance with federal law and (b) are not required to maintain records beyond those mandated by federal law for the purpose of product tracking and tracing.

2. NACDS is a 501(c)(6) trade association which represents traditional drug stores and supermarkets and mass merchants with pharmacies. NACDS' chain member companies include regional chains, with a minimum of four stores, and national companies. NACDS has fifteen (15) chain members in Florida who operate nearly 2,900 pharmacies. Member pharmacies help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability.

<sup>1</sup> NACDS has standing to file this Petition on behalf of its members pursuant to *Federation of Mobile Home Owners of FL, Inc. v. Dep't of Business Regulation, Div. of FL Land Sales, Condominiums and Mobile Homes*, 479 So. 2d 252 (Fl. 1985). As laid out below, NACDS demonstrates that its members operating in Florida are "substantially affected" by the laws in question, that this petition is within the scope of its mission and activity, and that the relief sought is of the type appropriate for NACDS to obtain on behalf of its members.

3. NACDS' mission is "to advance the interests and objectives of the chain community pharmacy industry, by fostering its growth and promoting its role as a provider of healthcare services and consumer products." NACDS accomplishes its mission by fostering "an advantageous business and political environment in which NACDS chain member companies are better able to achieve their business objectives," as well as providing "effective channels of communication" among members and between other stakeholders. *See* NACDS' website, Mission Statement at <http://www.nacds.org/aboutus/mission.aspx>.

4. NACDS headquarters are located at 1776 Wilson Boulevard, Suite 200, Arlington, Virginia, 22209, (phone) (703) 549-3001, (fax) (703) 836-4869. For the purpose of Petition, all pleadings and correspondence should be directed to its counsel, Mary Ellen Kleiman, [mkleiman@nacds.org](mailto:mkleiman@nacds.org), (phone) (703) 837-4327.

5. NACDS chain pharmacy members ("Members") purchase their prescription drugs either directly from the manufacturer or, in most instances, from wholesalers. When the pharmacy receives the purchased drugs, it also receives the 3Ts – transaction history, information and statement – that is to accompany those drugs, by law. However, there may be instances in which the 3Ts do not correspond exactly to the product received. For example, if there is a shortage, the number of drugs received may be less than the number of drugs reflected in the 3Ts. NACDS Members are not in control of the 3Ts that they receive from the manufacturer or wholesaler. To expose pharmacies to felony violations for receiving incomplete or inaccurate 3Ts, through no fault of their own, is inappropriate and unlawful. More specifically, to impose the obligation on NACDS Members in Florida which effectively requires them to ensure the correction of 3Ts upon receipt if they are not accurate nor complete is beyond the scope of federal law. Further, it would be exceptionally burdensome from a financial and operational perspective and would likely negatively impact pharmacy inventories and delay patient access to those prescription medications.

6. As referred to above, Members receive the 3Ts from the manufacturer or wholesaler for the

corresponding prescription drug purchase. But Members are not required to obtain other records as a part of that transaction, which would be in addition to or outside of the 3Ts. To impose that additional record keeping obligation on Members would result in additional administrative and record-keeping expenses and would require a re-allocation of resources and additional costs.

### **LAWS ON WHICH DECLARATORY JUDGMENT IS SOUGHT**

7. Under Florida law, pharmacies are required to obtain the 3Ts upon receipt of the prescription drugs they have purchased. 61N-1.031(1)(a), FAC. Further, the pharmacy “shall capture” the 3Ts “as necessary to investigate a suspect product” and maintain it for six (6) years. 61N-1.031(1)(c), FAC. This parallels the federal requirement, as described below in paragraphs 12 and 13.

8. Included in the 3Ts is “transactional information,” which is defined identically under Florida and federal law. *Compare* Rule 61N-1.028(27), FAC *with* 21 U.S.C. § 360eee(26). Under these identical definitions, “transactional information” includes only the following: proprietary name of the product; product strength and dosage; product National Drug Code Number; container size and number; product lot number; date of transaction and ship; and the names and addresses of the one sending and the one receiving the product.

9. Florida law also imposes an apparent additional documentary burden - - anyone engaged in the “receipt of . . . prescription drugs” must “maintain business records” pursuant to its obligations under Fl. Stat. Ann. Sec. 499.0121(6)(a)(2). This includes keeping “business records,” listed in § 499.0121(b)(1-7).<sup>2</sup> These records must be kept for six (6) years. *Id.* §499.0121(f).

10. Further, Florida law, FL. Stat. Ann. § 499.0051(1)(c), states as follows:

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<sup>2</sup> Far exceeding the definition of transaction information, *see* ¶8 *above*, this list includes the following: name and address of the seller; address of the location the active pharmaceutical ingredient or prescription drug was shipped from; distribution date of the active pharmaceutical ingredient or prescription drug; name, strength, and quantity, and the National Drug Code if such code has been assigned, of the distributed active pharmaceutical ingredient or prescription drug; name and Florida permit number of the person that purchased the active pharmaceutical ingredient or prescription drug; financial data, including the unit type and unit price, for the distributions involving active pharmaceutical ingredients or prescription drugs; and date and method of disposition of the active pharmaceutical ingredient or prescription drug.

(1) FAILURE TO MAINTAIN OR DELIVER TRANSACTION HISTORY, TRANSACTION INFORMATION, OR TRANSACTION STATEMENT.— \* \* \*

(c) Any person who knowingly destroys, alters, conceals, or fails to *maintain a complete and accurate* transaction history, transaction information, or transaction statement 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. (emphasis added)

11. Under Florida state law, a third degree felony may subject a person to up to five (5) years in prison, *see* Fl. Stat. Ann. § 775.082(e) and a five thousand dollar (\$5,000) fine, *see* Fl. Stat. Ann. § 775.083(c). *See also* Fl. Stat. Ann. §§ 775.084(4)(a)(3), (b)(3), (c)(1)(iii), (d)(3) (listing the prison terms of up to ten (10) years for “habitual offenders”).

12. Under the federal track and trace law, the Drug Supply Chain Safety Act, 21 U.S.C. § 360eee *et seq.* (“DSCSA”), dispensers are not permitted to “accept ownership of a product, unless the previous owner prior to, or at the time of, the transaction, provides” the 3Ts. 21 U.S.C. §360eee-1(d)(1)(A)(i).

13. The dispenser is required to “capture” the 3Ts to the extent “necessary to investigate a suspect product, and maintain” it for at least six years. *Id.* § §360eee-1(d)(1)(A)(iii); *see also* ¶ 7, *above*.

14. Failure to comply with these provisions is a prohibited act under 21 U.S.C. § 331(t) and could result in misdemeanor related penalties of up to one (1) year in prison or up to one thousand dollars (\$1,000) in fines. *See* 21 U.S.C. § 333(a)(1); *see also* 21 U.S.C. §331(a)(2) (increasing prison term up to three (3) years and fines up to ten thousand dollars (\$10,000) for repeat offenders).

15. Importantly, DSCSA preempts all state law as follows:

no State or political subdivision of a State may establish or continue in effect any requirements for tracing products through the distribution system (including any requirements with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution

system) which are *inconsistent with, more stringent than, or in addition to, any requirements applicable* under section 353(e) of this title or this part (or regulations issued thereunder), or which are inconsistent with—

- (1) any waiver, exception, or exemption pursuant to section 360eee or 360eee-1 of this title; or
- (2) any restrictions specified in section 360eee-1 of this title.

21 U.S.C. §360eee-4 (emphasis added).<sup>3</sup>

### **HOW THE STATUTES AND RULES MAY SUBSTANTIALLY AFFECT NACDS MEMBERS OPERATING IN FLORIDA IN THEIR PARTICULAR SET OF CIRCUMSTANCES**

16. NACDS Members are under a significant burden to comply with the federal requirements of capturing and maintaining the 3Ts under the DSCSA. While they seek to comply with these new track and trace obligations, they find benefit in the national program and standard under the DSCSA versus varying obligations under individual state requirements. Indeed, as reflected by the preemption language above, that was the intent of Congress in passing the DSCSA.

17. In Florida, however, NACDS Members are at risk for increased criminal penalties for failing to comply with additional obligations regarding completeness and accuracy of the 3Ts beyond that required by federal law. *Compare* FL. Stat. Ann. § 499.0051(1)(c) *with* 21 U.S.C. §360eee-1(d)(1)(A)(iii). They also have an obligation to maintain additional information/documentation beyond the federally prescribed scope of the 3Ts.

18. The consequences of these potential additional burdens are real for NACDS Members and the patients they serve. If procedures must be developed and implemented to meet additional state requirements, this will take significant resources, including both personnel and monetary, not anticipated as a part of track and trace compliance. The economic impact will be harmful. Further, once implemented, added paperwork and verification burden may have a large impact on patient access

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<sup>3</sup> The Department has previously recognized the preemption authority of the DSCSA. *See* Declaratory Statement *In re*: Petition for Declaratory Statement, Publix Super Markets, Inc., DS 2014-007, Filed April 15, 2014 found at <http://www.myfloridalicense.com/dbpr/ddc/documents/PublixSupermarkets.pdf> .



to needed medication as it could take longer for NACDS Members to incorporate the prescription drugs into pharmacy inventory. Failure to undertake these unduly burdensome steps, beyond what federal law requires, could leave an NACDS Member with state felony exposure.

19. NACDS Members need to have certainty and predictability in their obligations under track and trace law as intended by the DSCSA, but the provisions of Florida law presented herein threaten to defeat that purpose with provisions that may operate in a manner that is “inconsistent with, more stringent than, or in addition to, any [DSCSA] requirements applicable . . .” 21 U.S.C. §360eee-4.

20. First, Fl. Stat. Ann. §§ 499.0051(1)(c) imposes greater penalties, contrary to DSCSA, for failing to maintain the 3Ts, putting NACDS Members at risk for felony violations when similar violations are deemed misdemeanors under DSCSA. It also conflicts with federal law to the extent it requires different maintenance standards - - requiring maintaining “accurate” 3Ts versus maintaining 3Ts “necessary to investigate suspect product”. Florida’s accuracy requirement imposes additional felony liability on pharmacies if they maintain inaccurate 3Ts through no fault of their own. This is not permitted under the DSCSA. In each instance where state law conflicts with federal law, that would require preemption by DSCSA. *See* 21 U.S.C. § 360eee-4(a).


21. As for recordkeeping requirements for “business records” under § 499.121(6)(b), Florida adds additional documents to those included in the transaction information of the 3Ts. *See* 21 U.S.C. § 360eee(26); *see also* Rule 61N-1.028(27), FAC. This additional recordkeeping burden also is expressly preempted by DSCSA. *See* 21 U.S.C. § 360eee-4(a).

22. NACDS Members wish to avoid the additional administrative and operational burdens described herein that exceed the scope of their obligations under DSCSA and to avoid the risk of being subject to increased administrative or criminal proceedings violating Chapter 499 if they do not assume those burdens. Therefore, NACDS is justified in seeking this declaratory statement to clarify NACDS Member rights under the above statutes.

**Wherefore, NACDS requests that the Department issue a Declaratory Statement determining that:**

- a. When NACDS Members purchase prescription drugs from a manufacturer or wholesaler, their obligations to maintain the 3Ts received from manufacturers and wholesalers do not exceed their obligations under federal law.
- b. After NACDS Members purchase prescription drugs from a manufacturer or wholesaler, if they fail to maintain the 3Ts pursuant to those obligations, their liability does not exceed that applicable under federal law.
- c. When NACDS Members purchase prescription drugs from a manufacturer or wholesaler, they are not required to maintain "business records" related to that transaction that fall outside the scope of transactional information contained in the 3Ts, as prescribed by federal law.

Respectfully submitted this 17th day of October, 2016.

  
\_\_\_\_\_  
Mary Ellen Kleiman  
Don L. Bell, II  
National Association of Chain Drug Stores  
1776 Wilson Blvd.  
Suite 200  
Arlington, VA 22209

**Certificate of Service**

I hereby certify that the original of the foregoing Petition for Declaratory Statement was mailed first-class, postage prepaid to the Agency Clerk, Department of Business & Professional Regulation, 2601 Blair Stone Road, Tallahassee, FL 32399-2202, with a courtesy copy via email to Reginald Dixon, Executive Director, Division of Drugs, Devices, and Cosmetics at ([reggie.dixon@myfloridalicense.com](mailto:reggie.dixon@myfloridalicense.com)) this 17<sup>th</sup> Day of October, 2016.