Aug. 14, 2017

Robert Hinchman
Senior Counsel
Office of Legal Policy (OLP)
U.S. Department of Justice
950 Pennsylvania Avenue NW Room 4252
Washington, DC 20530

Re: Request for Public Comment: Enforcing the Regulatory Reform Agenda; Department of Justice Task Force on Regulatory Reform Under E.O. 13777 (Docket No. OLP 164)

Dear Mr. Hinchman,

The Healthcare Distribution Alliance (HDA) is pleased to provide input in response to the solicitation of input by the Department of Justice’s Regulatory Reform Task Force (Task Force). We commend your effort to evaluate the current circumstances and identify regulatory issues that merit attention from the Department of Justice.

HDA represents primary pharmaceutical distributors, the vital link between the nation’s pharmaceutical manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. HDA and its members work daily to provide value and achieve cost savings for our nation’s healthcare system. HDA previously was known as the Healthcare Distribution Management Association (HDMA).

HDA members are regulated by the Drug Enforcement Administration (DEA) and, in their business operations, interact daily with other DEA-regulated entities. Our comments here are limited to regulatory activities implementing the Controlled Substances Act (CSA). We are fortunate to enjoy a strong relationship with DEA’s Diversion Control Division. We offer these comments with the shared ongoing goals of assisting HDA members to understand and comply with their responsibilities under the CSA, and contributing to solutions to reduce the abuse and misuse of controlled substances—including opioids—while also allowing prescribers and patients timely access to those important medicines in cases of legitimate medical need. HDA applauds the Administration’s focus on finding solutions to the opioid epidemic, including its work across numerous departments and offices to provide assistance to those who need it most.
In the notice, the Task Force seeks comment for two purposes. First, the Task Force seeks comments “on the various kinds of actions taken by the Department’s components that the public perceives to be regulatory in nature even if they are issued in a form other than rules promulgated upon notice and comment.” Second, the Task Force “seeks suggestions from the public for specific regulatory actions . . . that should be repealed, replaced, or modified, consistent with applicable law. In particular, the Task Force welcomes specific comments that identify regulatory actions that meet the criteria as proscribed in Executive Order 13777.”

We address both aspects of the Department’s request in this comment. In section I, we recommend several regulatory changes that would meet the goals of Executive Order 13777. In section II, we highlight an additional two changes that would reduce costs to the government and to regulated industry, but which do not require regulatory changes. In section III, we discuss actions by Department components that appear to be regulatory in nature although they occur outside of notice and comment rulemaking.

We hope that our comments are useful to you, and stand ready to provide additional input or assistance as your task force proceeds.

I. Specific Regulatory Actions Taken by the Department that Should Be Repealed, Replaced, or Modified.

Consistent with the language in Executive Order 13777, in this section we highlight regulatory actions that:

- eliminate jobs, or inhibit job creation;
- are outdated, unnecessary, or ineffective;
- impose costs that exceed benefits; or
- create a serious inconsistency or otherwise interfere with regulatory reform initiatives and policies.

A. Revise the Suspicious Orders Monitoring and Reporting Regulation.

Wholesale distributors understand their critical role in the effort to stop controlled substances from reaching pharmacies and practitioners that will divert them to inappropriate uses. As logistics companies who take seriously their responsibility to be part of the solution, primary pharmaceutical distributors have invested heavily in information technology systems to help better flag suspicious ordering patterns, have engaged team members to track and monitor pharmacy orders, and continue to support efforts designed to improve coordination and communication with DEA.

Over the past 11 years, DEA has evolved and refined its expectations for wholesale distributors in monitoring for and reporting suspicious orders. While the longstanding and simple language in 21 C.F.R. § 1301.74(b) has remained constant, DEA has interpreted that language in letters to industry in 2006 and 2007 and through language in adjudicatory orders, including one in
Through similar means over recent years, DEA also has expressed evolving expectations for distributors’ maintenance of “effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels,” as required by 21 U.S.C. § 823. For instance, in a 2006 letter DEA expressed its expectations that registrants will conduct “due diligence” as part of their statutory compliance. At a later DEA-hosted industry conference, DEA provided examples of questions to ask potential customers for “know your customer” purposes. DEA has not incorporated these expectations into regulations.

Further, while DEA has expressed that the “know your customer” requirements are distinct from the suspicious order reporting requirements, the distinctions are not always clear. In practice the two types of investigations are inextricably linked.

In light of DEA’s ongoing interpretation of the scope of 21 C.F.R. § 1301.74(b), and the blurring of the 21 U.S.C. § 823 “effective controls” requirement with the suspicious orders monitoring requirement, HDA respectfully suggests that 21 C.F.R. § 1301.74(b) is outdated and may be ineffective as written. HDA recommends that DEA consider revising that regulation pursuant to Executive Order 13777. We believe that the agency may have begun this activity already and note that we have raised certain related issues with agency staff in past communications. In revising the regulation, HDA recommends that DEA consider making the following clarifications.

1. **Clarify Factors and Analysis Relevant to Due Diligence and Suspicious Orders.**

HDA suggests that in revising 21 C.F.R. § 1301.74(b), DEA provide clarity in the following areas, while still allowing registrants flexibility in designing systems to meet the requirements.

**Parameters & Outer Limits of Due Diligence and Suspicious Orders Considerations.** In revising 21 C.F.R. § 1301.74(b), HDA suggests that DEA attempt to define the general parameters and the outer limits of both the “due diligence” and “suspicious orders monitoring” evaluations. By using notice and comment rulemaking to broadly define the types of factors that wholesale distributors should consider in both evaluations, DEA could receive clarifying input from regulated industry that could help improve the robustness and actionability of the resulting framework. Over time, DEA has identified numerous factors for registrants to consider in assessing the validity of customers and/or orders. In the 2006 letter, for instance, DEA identified a long list of “circumstances that might be indicative of diversion.” That list remains one of the clearest utterances from DEA on the topic, but it has serious limitations. The factors identified in that list are difficult to apply to customers other than retail pharmacies, and DEA has not updated the list to reflect input from distributors relating to their capabilities, changing practices, and market dynamics.

In a rulemaking proceeding, wholesale distributors could help ensure that the resulting regulation does not include factors that lie outside of wholesalers’ information and capabilities. Many HDA members have considered these issues carefully as they have developed...
increasingly advanced due diligence and suspicious orders monitoring systems. For instance, it may overestimate the capabilities of wholesale distributors to ask them to consider whether the pharmacy “offers to facilitate patient relationships with prescribers with whom the patient has no prior relationship” or “fills prescriptions issued by practitioners based solely on an online questionnaire,” as DEA suggested in the 2006 letter.9 Similarly, given the ever-evolving complexities of insurance markets and coverage, wholesale distributors are limited in their ability to determine “whether the pharmacy pays more for controlled substances than insurance will reimburse,” as DEA suggested in an adjudicatory order.10

In the course of a rulemaking, regulated industry also may help DEA understand which factors are relevant in examining non-pharmacy customers, including hospitals, dental offices, physician’s offices, and veterinary practices. In its past statements, DEA generally has focused on the retail pharmacy customer.11

Moreover, such a rulemaking could lead to improved consideration of anti-trust, patient confidentiality, and other legal and employee safety considerations in DEA’s requirements. For instance, a wholesale distributor’s suspicious orders monitoring system examines the product orders received by that company, but cannot evaluate data across industry competitors because obtaining such information may be counter to federal anti-trust laws. Thus, a wholesale distributor does not have access to certain data that DEA suggests considering, such as patterns of ordering involving industry competitors.12

Finally, DEA might use the rulemaking to better distinguish the factors that are to be considered when conducting due diligence versus those to be used in assessing whether an order is suspicious. While DEA has said that the two investigations have different bases, DEA has not always clearly articulated the distinctions between the two.13 If DEA intends registrants to use the same factors in both considerations, DEA also might clarify whether registrants should weigh them differently or apply a higher threshold for different analyses.

**Multi-Step Suspicious Orders Systems.** HDA recommends that, in revising its regulation, DEA allow registrants flexibility in designing multi-step systems to identify suspicious orders. While a registrant might create a one-step system in which the registrant reports every order identified by a computer algorithm as suspicious, many current suspicious orders monitoring systems evaluate orders in two steps, and future technological advancements may allow for additional steps in the evaluation, with each step increasing in analytical refinement.

HDA also recommends that DEA’s regulations acknowledge the variation within multi-step systems. The systems that wholesale distributors have developed over the past several years vary in their approaches because they were developed independently by market competitors. In some registrants’ systems, a computer algorithm may flag orders as suspicious, with a manual investigation supporting or disproving the system’s conclusion. Other registrants may have designed their algorithm to flag a broader range of orders so that staff can manually review (and maintain awareness of) more orders. In these systems, orders flagged in the first
step may not be considered suspicious. The later steps of the monitoring system, involving manual review by experts within the company, may be the point at which an order is properly deemed “suspicious.” DEA should ensure that its revised regulation accommodates the full range of different approaches that could be used to determine that an order is suspicious.

**Data Analysis.** HDA members also would appreciate further information about DEA’s expectations and suggestions for analyzing the data they collect. In defining factors for registrants to consider, DEA has used terms such as excessive, reasonable, disproportionate, and limited—terms that must be subject to interpretation, in part due to the significant differences between types of customers (e.g., hospital, retail outpatient pharmacy, dentist office, or veterinarian). Still, HDA members welcome suggested criteria and methodologies for evaluating the legitimacy of both the order and the customer, as well as information about DEA’s expectations regarding the updating of customer information. While DEA may have communicated such expectations individually to certain wholesale distributors, such expectations must be shared with the industry generally to be effective.

As one example, HDA members would benefit from guidance regarding orders that become suspicious only over a period of time, in the context of the regulation’s requirement to report a suspicious order “when discovered.” Orders which grow by apparently insignificant amounts order-by-order may, over time, achieve a size that necessitates further inquiry and reporting as suspicious. While a retrospective “should have known” standard may provide the agency with desired flexibility for enforcement purposes, it does not provide meaningful guidance for registrants seeking to address these challenging situations prospectively. Illustrative examples provided through the rulemaking process would be useful.

2. **Discuss Resolution of Red Flags.**

HDA suggests that DEA clarify whether, in a multi-step suspicious orders monitoring system, the agency wishes registrants to conduct a “totality of the circumstances” evaluation or strictly to resolve every “red flag.” DEA’s directives on this topic do not lead to one clear conclusion, as DEA has stated that “[d]istributors should consider the totality of the circumstances when evaluating an order for controlled substances,” that the investigation must “dispel the suspicion,” and that the answer to any one question will not “necessarily determine whether a suspicious order is indicative of diversion to other than legitimate medical channels,” but also that the investigation must “dispel all red flags.”

HDA recommends that DEA continue to ask registrants to use a “totality of the circumstances” evaluation for red flags. While it may seem straightforward to instruct that the registrant must report an order as suspicious unless the registrant resolves all “red flags” that gave rise to the suspicion, implementing such a requirement is extremely complex, especially in light of the factors identified by DEA in its various statements. If all the factors listed by DEA in its various communications constitute “red flags,” a directive to resolve “all red flags” could result in a dramatic increase in the number and scope of orders being reported, but may not increase the
number of meaningful reports. For instance, the acting Administrator has specified that a DEA registrant cannot “ignore information it has obtained as to the scope of drug abuse in a particular area.” If the rate of local drug abuse is a “red flag,” it would seem never to be possible to resolve “all red flags” for orders originating in areas suffering from significant drug abuse, regardless of the outcome of the investigation otherwise.

3. Improve Information-Sharing from DEA to Registrants.

As wholesale distributors work to identify healthcare entities that are likely to divert controlled substances and to prevent those entities from receiving controlled substances, they seek to receive as well as share information in partnership with DEA. With proactive disclosure of relevant information by DEA, registrants could further improve their forward-looking controls against diversion, increasing their efficiency in the collaborative fight. In order to improve the analysis of customers and orders, HDA suggests that the following clarifications from DEA would be helpful.

First, we recommend that DEA provide wholesale distributors with aggregated purchasing data from the ARCOS (Automation of Reports and Consolidated Orders System) database. Under 21 C.F.R. § 1304.33, distributors must report inventories, acquisitions, and dispositions of all substances in Schedules I and II, and narcotic substances in Schedule III, on at least a quarterly basis. In the past, Diversion Control Division officials have indicated that DEA would need to amend its regulations in order to disclose this information. Because this information would improve industry’s efficiency in preventing diversion, and because the non-disclosure of this information imposes costs on society, HDA recommends that DEA take the regulatory actions necessary to begin sharing this data.

ARCOS disposition data, if provided by DEA in aggregate form without identifying competitor distributors, could allow wholesale distributors to consider a customer’s orders in the context of that entity’s overall ordering. This would provide additional data points in determining whether an order is suspicious. In previously asking DEA to share ARCOS data, HDA also has explained to DEA that such data could:

- Help indicate the drugs that distributor registrants should watch most carefully;
- Help in the increasingly difficult effort to detect trends and patterns solely by evaluating each company’s data individually;
- Help in identifying individual practitioners’ orders of interest, which are much less frequent than retail pharmacies or large health care entities (e.g., hospitals) and therefore more difficult to analyze for trends.

After creating more rigorous suspicious orders monitoring systems, some wholesalers noted a decrease in “large” orders, and an increase in the number of wholesalers used by individual dispensers. Thus, this additional data not only would help fill one of the largest gaps in the data analyzed by distributors, but also has become even more important as time has progressed.
Second, HDA asks that DEA define the circumstances in which a wholesale distributor may request information on a (questionable) customer from DEA, the information that DEA would provide in response to such a request, and the timeframe for receiving that information. HDA members understand that DEA will never tell them not to ship to a particular customer (unless that entity’s DEA registration has been suspended or revoked), and that the agency will not disclose information relating to current investigations. Nevertheless, HDA members believe that, through dialogue, we might mutually identify information held by DEA that could assist wholesale distributors to know their customers.

Third, HDA would like to work with the agency to identify the criteria and conditions under which DEA could proactively provide a wholesale distributor with relevant information about a potential customer. For instance, HDA understands that, at times, DEA may possess relevant data or other information about a healthcare facility that would help HDA members fulfill their responsibilities under 21 U.S.C. § 823. Any such sharing of information in a forward-looking way can help wholesale distributors prevent opioids and other controlled substances from being diverted to illegitimate purposes.

### B. Reduce Duplicative Registrations by Allowing Registrants to Handle Strong Iodine Under Their Controlled Substance Registrations.

Under the current DEA registration requirements, a wholesale distributor may possess and distribute controlled substances in schedules II, III, IV, and V, and also products containing the listed chemicals ephedrine and pseudoephedrine, under a single DEA controlled substance registration. In order to also receive and distribute a 7% iodine solution to a veterinary customer, however, that distributor must obtain a separate listed chemical registration from DEA. This requirement is redundant and unnecessary, and imposes costs that exceed its benefits, so should be revised.

While the regulations in 21 C.F.R. part 1309 relating to chemical registrations—and the statutory language they implement—are not a model of clarity, DEA helpfully provided guidance, stating in a letter to industry:

> DEA controlled substance registrants are not permitted to distribute List I chemicals utilizing their DEA controlled substance registrations unless they meet the specific requirements of Title 21 [C.F.R.] 1309.24(b). . . . Therefore, controlled substances manufacturers, distributors, and dispensers of these materials must obtain a separate chemical registration to handle regulated forms of iodine. . . . If your business is handling iodine over 2.2 percent, is not registered by DEA to handle List I chemicals, or did not apply for such registration by the August 31, 2007 deadline, it must cease activity in this area.  

HDA does not discount that “seven percent iodine tincture and solutions are the predominant iodine-containing chemical mixtures diverted by traffickers.” Such products remain on the
market, are useful in large animal veterinary practice, and are distributed by HDA members in accordance with DEA’s requirements, however.

For wholesale distributors that already possess a DEA controlled substance registration, the requirement for a separate listed chemical registration is a matter of paperwork. Even in the absence of such a separate and additional registration, the registrant handling the 7% iodine solution is bound to comply with the listed chemical reporting and recordkeeping requirements in 21 C.F.R. part 1310 and the security requirements in 21 C.F.R. § 1309.71. Wholesale distributors that hold DEA registrations to handle controlled substances—and are entitled to handle drug products containing the list I chemicals pseudoephedrine and ephedrine under those controlled substance registrations—are experienced with and capable at providing product security and preventing and detecting diversion. Moreover, while DEA mentioned in regulating 7% iodine that “A business that sells a List I chemical in violation of the law or regulations can have its registration revoked and be prevented from handling List I Chemicals,” we note that a controlled substances registrant faces the even more dire prospect of having its controlled substance registration revoked over an iodine violation.

Moreover, this requirement for duplicative registrations impacts inventory and invoicing systems, adding implementation costs that are not necessary to realize the benefit of regulation. Including a listed chemical registration number in records, and maintaining records for that registration separately from the records linked to the controlled substance registration, requires additional database complexity.

Therefore, to eliminate this unnecessary and ineffective regulatory requirement, HDA suggests expanding the language in 21 C.F.R. § 1309.24 to waive chemical registration for this group of DEA controlled substance registrants:

Any person who manufactures or distributes a product containing a List I chemical that is not described and included in paragraph (1)(iv) of the definition of regulated transaction in §1300.02 of this chapter, if that person is registered with the Administration to engage in the same activity with a controlled substance.

C. Update Regulations to Reflect Statutory Changes.

Recently, Congress has made two relevant changes to the CSA. For the sake of clarity, HDA encourages DEA to change its regulations to reflect the statute.

First, in its efforts to combat the opioid crisis, HDA encourages DEA to incorporate into the dispensing regulations in 21 C.F.R. part 1306 the recent changes to 21 U.S.C. § 829(f) allowing pharmacists to partially fill a prescription for a schedule II controlled substance at the patient or prescriber’s request. Partial-filling of prescriptions strikes an appropriate balance, in that it can help prevent the buildup of unused medications in home medicine cabinets, thereby preventing diversion, but also allows patients to access the full amount of medication prescribed by a practitioner should they need it. While the Unified Regulatory Agenda indicates that DEA is working on certain regulatory changes to implement other sections of the Comprehensive
Addiction and Recovery Act of 2016, it is not clear whether DEA is including the partial-fill changes in that rulemaking. HDA encourages DEA to make this simple change sooner rather than later, in light of the national focus on reducing opioid use, abuse, and diversion.

Second, HDA recommends that DEA revise its hearing procedures in 21 CFR part 1316 to reflect the recent changes to 21 U.S.C. § 824(c), allowing a registrant to submit a corrective action plan upon receipt of an order to show cause. While the statutory text is effective without being incorporated into the regulations, the procedures for administrative hearings will be more clear for all parties once DEA has revised part 1316 to fully reflect the statute. HDA is aware that the procedures in part 1316 apply broadly to a wide variety of administrative proceedings, including formal adjudications of quota challenges and formal rulemaking for scheduling actions, and that revising part 1316 to incorporate the new statutory language might be best achieved by creating distinct procedures for each of those types of proceedings. DEA has included this action in the Unified Regulatory Agenda, and we encourage DEA to continue moving forward with this change.

D. Continue Efforts to Update Regulations Governing Electronic Prescribing of Controlled Substances.

HDA encourages DEA to take actions to encourage prescribers use secure electronic means to prescribe controlled substances, rather than paper prescription pads. Electronic prescribing of controlled substances (EPCS) can be an important tool in stemming the opioid crisis, in that it can help reduce prescription fraud, can safeguard against “doctor shopping,” and can improve the data in prescription drug monitoring programs.

In each of its recent Unified Regulatory Agendas until the most recent, DEA has stated its intent to revise the EPCS regulations. DEA described its plan to modify and finalize its interim final rule on EPCS in part to clarify “the criteria by which DEA-registered practitioners may electronically issue controlled substance prescriptions.” DEA further noted that the final rule “would modify the requirements that must be met by any registrant who wishes to dispense controlled substances pursuant to electronic prescriptions, including requirements pertaining to authorized software applications.” Some commentators have suggested that “the many standards contained in the [DEA EPCS] make it cumbersome to implement,” specifically noting as a “hurdle” the requirement for prescriber identity proofing, even while discussing the many benefits of e-prescribing.

In 2016, only about 14% of prescribers were enrolled and able to use EPCS, meaning that the overwhelming majority of controlled substance prescriptions are still issued using paper prescription pads. Whether DEA’s best course is to update the EPCS regulations (issuing a new notice of proposed rulemaking if necessary, given the changes in technology since DEA published the prior proposed rule in 2008) or to educate prescribers about the ways in which they might utilize EPCS, HDA encourages DEA to identify and take the appropriate steps to streamline the EPCS process to address physician concerns about administrative burden and
time constraints. Streamlining the EPCS process and addressing physician work-flow concerns would encourage adoption of this technological method of reducing prescription opioid abuse.

**E. Allow Slightly More Time for Reverse Distributor Destruction of Waste.**

HDA encourages DEA to revise 21 C.F.R. § 1317.15(d) to slightly increase the amount of time that DEA-registered reverse distributors have to destroy controlled substances received for the purpose of destruction. The regulation currently requires destruction within 30 days of the date of receipt. We recommend expanding this to at least 45 days, as the current requirement imposes costs that are disproportionate to the benefits.

When DEA expanded the options for disposal of controlled substances in 2014, the agency also created new restrictions on DEA-registered reverse distributors that have increased the cost and logistical complexity of their longstanding activities. For instance, before the 2014 final rule, DEA imposed no time restrictions on reverse distributors. In implementing the 30-day limit, DEA noted its concern about accumulation of non-returnable controlled substances at the reverse distributor’s facility.

Our colleagues in the reverse distribution industry inform HDA that facilities generally operate on a monthly calendar, not a 30-day calendar. Healthcare facilities and pharmacies arrange to transfer their pharmaceutical returns to reverse distributors on a monthly basis. Reverse distributors in general schedule monthly destruction appointments with their contracted incinerator, as most DEA-registered reverse distributors do not operate their own destruction facility.

As a result, if the prior month had 31 days, the reverse distributor would technically be out of compliance with the 30-day destruction requirement in § 1317.15(d) on the day of destruction. Similarly, holidays—particularly in May, July, November, and December—can cause minor disruptions to the schedule that require a reverse distributor to store controlled substances for 31, 32, or even 33 days before destruction at the contracted incinerator facility.

While, in theory, a reverse distributor could schedule a second destruction appointment in those months containing 31 days or with holidays, this solution would impose disproportionate costs. Incineration facilities impose minimum charges, and for many reverse distributors, each of the two loads in a single month are likely to trigger that minimum charge. Moreover, since DEA requires two employees of the DEA-registered reverse distributor to accompany the controlled substances and to witness the destruction, a second destruction event during a month imposes significant personnel costs.

Extending the destruction timeframe to 45 days (or more) would provide needed flexibility, would continue to limit the accumulation of non-returnable controlled substances by reverse distributors, and would reduce the cost of destruction, which is borne by all participants in the pharmaceutical supply chain.
F. Revise Parts 1316 and 1321 To Permit Filing by Electronic Means, including Email.

HDA encourages DEA to revise its regulations in 21 C.F.R. parts 1316 and 1321 to allow documents in all enforcement and administrative proceedings to be filed by electronic means, including email. Such allowances would obviate the logistical and security challenges presented by physical delivery of filings at the DEA address of record. While physical delivery by U.S. Postal Service or commercial service can be preserved as an option, electronic filing would reduce the cost to the DEA of securely handling physical mail, would reduce processing time and should increase efficiency. This change also would reduce expense to persons filing in enforcement and administrative proceedings. It aligns with the practices of the U.S. federal courts, which have successfully moved to electronic case filing with certain limited exceptions such as filing under seal. In considering the objectives of Executive Order 13777, HDA believes that the costs certainly exceed the benefits of requiring physical delivery of documents.

II. Actions That Would Reduce Costs Without Requiring Regulatory Changes.

A. Make Changes To CSOS To Encourage Use of Electronic Ordering Instead of Triplicate Forms.

HDA encourages DEA to modify the Controlled Substance Ordering System (CSOS) to assist registrants to use that electronic system rather than the longstanding triplicate paper Form 222 order forms. While we believe that the paper Form 222 should always be available as a backup, the CSOS presents a more efficient option and should be the primary method of ordering schedule II controlled substances moving forward. CSOS has been in place for 12 years, yet ongoing technical issues mean that many transactions in schedule II controlled substances still must begin with a triplicate paper form.

As HDA has previously noted, greater use of CSOS should result in cost savings to the healthcare supply chain in the multi-million dollar range. Increased use of CSOS can improve patient care by facilitating faster receipt of orders and by streamlining management of the ordering system. The safeguards built into the electronic system are intended to enhance information security over the paper based system. Moreover, as DEA stated in 2005, with CSOS, “Electronic orders will be received almost instantly and can be shipped the same day. This speed may allow purchasers to . . . limit the quantity of controlled substances that they stock. Limiting the quantity of Schedule I and II controlled substances in stock reduces the possibility of diversion and the cost of security.”

1. Simplify CSOS To Ease Pharmacy Participation.

HDA understands that certain complexities in the CSOS prevent many pharmacies from using the electronic option to the extent that they could. HDA supports the recommendations made by our colleagues in the pharmacy sector, because wholesale distributors face greater costs and complications when a pharmacy places an order using a paper Form 222 instead of CSOS.
In particular, HDA supports the suggestion by the National Association of Chain Drug Stores (NACDS) that DEA institute an electronic or automated process for CSOS enrollment and renewal. NACDS has previously identified for DEA some of the logistical challenges associated with the current CSOS enrollment and renewal processes:

- The established procedures for receiving and coordinating access codes and passwords in 21 C.F.R. § 1311.25(c) create significant challenges when a pharmacy chain enrolls or renews multiple pharmacies in a short timeframe. DEA sends the access codes and passwords by different delivery methods, such as one by postal mail and one by email. Oftentimes DEA sends the information piecemeal by a variety of formats. A chain pharmacy that is coordinating renewals centrally faces a significant challenge in sorting through the various communications to match up access codes and passwords.
- The CSOS certificate retrieval process is extremely arduous. After the access codes and passwords have been entered, the retrieval process requires the user to have clicked a mouse 32 times, and to have entered information or answered acknowledgements with each click.
- Related to the issue above, when users are working to pull certificates from the CSOS portal, the portal will often time out and lock out the user for as long as 30 minutes before the user may log back in.
- DEA allows a pharmacy to renew its registration 60 days prior to expiration, and it generally takes DEA 30 to 40 days to process the renewal. By the time DEA processes the registration and sends the CSOS certificates, pharmacies can be left with only a week to get the certificates up and running at each pharmacy location. This can be challenging for a chain operating many stores, even when there are no technical difficulties with loading the certificates.

To resolve these ongoing challenges, NACDS has urged DEA to create an automated process in which the passwords for CSOS certificate retrieval can be uploaded into the certificate retrieval system. NACDS has asked that DEA update its software to eliminate the need for passwords to be issued in text files. In addition, NACDS has asked that the automated process allow a user to be logged in for extended periods of time.

NACDS also has mentioned to DEA that chain pharmacies would appreciate the ability to add and delete pharmacy locations as they open and close to the same coordinator, as well as the ability to manage staff departures by revoking CSOS credentials. NACDS has stated its belief that an online web portal would streamline and better facilitate CSOS processes and has urged DEA to consider the development of such an online enrollment and management tool for DEA registrants.

HDA supports NACDS’s suggestions regarding CSOS, as any steps that increase CSOS utilization by chain pharmacies will reduce the burden on wholesale distributors.
2. Allow Practitioners and Pharmacies To Use CSOS To Transfer Products to Distributors.

HDA recommends that DEA update CSOS to allow distributors to submit orders electronically to pharmacies and practitioners for the purpose of recall, return, or disposal. We believe that DEA can add this capability without changing its regulations, as 21 C.F.R. part 1311 includes no language that prevents this activity. Expanding the use of CSOS would reduce risks, in that it would allow pharmacies and practitioners to remove unwanted product from their inventory more quickly. In addition, as noted above, reducing use of the paper Form 222 would reduce the security concerns presented by paper forms and would reduce costs in the healthcare supply chain.

At present, only those registrants that report to ARCOS are eligible to fill orders placed using CSOS, under DEA’s technical specifications. Yet only manufacturers and distributors report to ARCOS under 21 C.F.R. § 1304.33(c). As a result, in general, CSOS can be used only for the forward movement of a schedule II controlled substance through the supply chain, i.e., manufacturer to distributor to pharmacy/practitioner.

Returns, recalls, and disposal/destruction of a product from a registrant’s stock—the “reverse distribution” aspect of the supply chain—represent significant movement of pharmaceuticals in the U.S. Around 3.5 - 4% of all drugs ordered annually, equaling about 120,000,000 units, are returned due to over-ordering, product expiration, recall, or other reason. While only a percentage of these returns are of schedule II controlled substances, such returns are made from virtually all of the 66,934 registered pharmacies and many of the more than 1,100,000 registered practitioners and hospital/clinics. Each shipment of a schedule II controlled substance from each such registrant—literally thousands of shipments per year—requires a distributor to complete and submit a paper Form 222 because DEA prohibits pharmacies and practitioners from filling electronic orders for technical reasons.

HDA understands that when the agency initially introduced CSOS, DEA intended to expand the system to be usable by entities that do not report to ARCOS. HDA encourages DEA to move forward with that change.

In addition, HDA suggests that DEA revise 21 C.F.R. § 1305.06 to allow dispenser registrants, including pharmacies, hospitals, and physician offices, to fill an order submitted by a registered reverse distributor. That section, which allows dispensers to send schedule II controlled substances only back to the supplier unless the dispenser is discontinuing business, is inconsistent with 21 C.F.R. § 1317.05(a)(2) & (b)(2), which allow the dispenser to deliver controlled substances to a reverse distributor’s registered location for disposal. DEA’s approach in part 1317 is preferable to that in section 1305.06 because it increases efficiency and reduces the number of entities handling controlled substances being processed for disposal, thereby reducing risks. While wholesale distributors are able to accept returned medications for the purpose of disposal, it would be more efficient for dispensers to send those
products directly to reverse distributors. DEA-registered reverse distributors have made significant investments in systems and infrastructure, meaning that the requirement to send schedule II controlled substances first to a distributor for processing, and then to a reverse distributor for disposal, imposes costs well exceeding any benefits.

3. **Implement a 24-Hour Contact Number for Reporting Unexpected CSOS Outages.**

HDA recommends that DEA create and make available a specific telephone number for reporting unexpected CSOS outages that occur overnight or on weekends.

Wholesale distributors are active around the clock, seven days a week. The CSOS service desk is available 8:00 AM through 5:50 PM Eastern Time Monday through Friday. HDA understands that the service desk receives a range of inquiries, from questions about registration to detailed questions about how to complete an order form, and that providing 24-hour customer support may be unnecessary and inefficient.

Because aspects of the pharmaceutical supply chain operate on a “just-in-time” basis, however, an outage of the CSOS system can create significant and dramatic challenges, potentially affecting patient care.

At present, one member of the Diversion Control Division’s leadership team has provided her cell phone number for use in case of an unexpected, out-of-hours CSOS outage. HDA members are grateful for her willingness to assist. To assure consistency in case of personnel changes, however, HDA believes that establishing and publishing a permanent telephone number—for use only in case of unexpected, out-of-hours CSOS outages—would be the best course of action. Such number, of course, might be forwarded to the cell phone of the appropriate “on call” individual.

**B. Establish an Ombuds Office.**

HDA suggests that DEA consider creating an ombuds office as described in the recent recommendation by the Administrative Conference of the U.S. (ACUS), *The Use of Ombuds in Federal Agencies*. The DEA ombuds office, which would be separate from the Diversion Control Division and could report to the Deputy Administrator, would allow regulated industry to “raise issues confidentially and receive assistance in resolving them.” As ACUS notes, “Constituents and the agency are served by the ombuds’ skilled, impartial assistance in resolution, and the agency is served by the opportunity for critical early warning signs of specific and systemic issues.” Among other benefits, ACUS notes that ombuds offices “contribute to significant cost savings by dealing with identified issues, often at the earliest or pre-complaint stages, thereby reducing litigation and settling serious disputes.” A DEA ombuds office, of course, would “not make decisions binding on the agency or provide formal rights-based processes for redress” and would not be “a conduit for notice to the agency,” but would “provide credible processes for receiving, reviewing, and assisting in the resolution of issues.”
III. Actions Taken by the Department’s Components That the Public Perceives To Be Regulatory in Nature.

In this section, in response to the Task Force’s request for information regarding “the various kinds of actions taken by the Department's components that the public perceives to be regulatory in nature,” including those that “impose[] binding requirements on any person or entity outside the federal government or . . . state[] criteria that a Department component will use to assess compliance with such a binding requirement,” HDA discusses DEA’s use of adjudication procedures to express policy, and its expressions of policy outside of notice and comment rulemaking procedures. DEA recently acknowledged that it uses both such methods to establish policy interpretations for use in future adjudicatory proceedings:

The Administrator’s decision in this [adjudication relating to Masters Pharmaceuticals] is consistent with the agency’s prior interpretations of both the CSA and the suspicious-order regulation. Indeed, the decision relied explicitly on both [the prior adjudication relating to] Southwood and the guidance letters. See 80 Fed. Reg. at 55,421 (discussing guidance letters), 55,475-77 (discussing guidance letters and Southwood). 41

A. Policymaking Through Adjudication

DEA has used adjudicatory orders to set policy and to define DEA’s interpretation of the CSA and its own regulations. For instance, in one recent adjudicatory order, the acting Administrator “explained what a distributor . . . must do if, instead of immediately reporting to DEA all orders of an unusual size, frequency, or pattern, it chooses to use the [suspicious orders monitoring system]—or equivalent program—to seek to dispel the suspicion. . . .” 42 As noted above, in the recent Masters adjudication, the acting Administrator explicitly relied on the interpretations that the Administrator had announced in the prior Southwood adjudication.

We raise this topic not to discuss the legal issues surrounding such policymaking, but instead to point out that notice and comment rulemaking can present certain advantages when setting generally applicable forward-looking policy. In contrast, DEA’s practice of formulating and publicizing policy interpretations through adjudication can create certain challenges for DEA registrants who are trying to understand and meet DEA’s expectations.

One benefit of notice and comment rulemaking is the clarity provided. As one scholar put it, “the articulation of a generally applicable rule provides greater clarity to those affected as well as greater uniformity in enforcement.” 44 In other words, industry and agency staff alike can have difficulty deciphering and implementing statements buried deep in orders. Because DEA intermingles comprehensive facts, interpretations, and judgments within its adjudicatory orders, it can be difficult to discern whether the agency is restating previously-established policy interpretations, modifying them slightly, or announcing new principles. The clear articulation of policy within notice and comment rulemaking—accompanied by preamble text—reduces such ambiguities.
Notice and comment rulemaking presents efficiencies for the agency, as well. It allows the agency to gather information from regulated industry, but still shape the conversation and content. With the benefit of additional information when drafting, the agency may be able to avoid revisiting or refining its positions for workability. Notice and comment rulemaking also allows the agency to formulate forward-looking policy without waiting for issues to arise within an adjudication and without the burdens of individual adjudicative issues.

Finally, regardless of DEA’s future procedural approach, HDA suggests that the Diversion Control Division consider revamping its website (deadiversion.usdoj.gov) to allow for improved navigation of DEA adjudication materials. The ability to find information in previously issued adjudicatory orders is particularly significant because of the policy interpretations they contain.

At present, final orders relating to DEA registrations are available on the Diversion Control Division’s website, but navigation is difficult and the orders are not easily searchable. The list of final orders issued in each year is presented on a separate page of the website, in the form of a list showing only the name of the registrant and date of issuance. No other information is provided, requiring a user to click on each final order to obtain its details.

ACUS recently considered the topic of adjudication materials on agency websites, offering “best practices and factors for agencies to consider as they seek to increase the accessibility of adjudication materials on their websites and maintain comprehensive, representative online collections of adjudication materials.” Of special note among the recommendations, ACUS recommended that:

Subject to considerations of cost, agencies should endeavor to ensure that website users are able to locate adjudication materials easily by . . . offering relevant filtering and advanced search options in conjunction with their main search engines that allow users to specify with greater detail the records or types of records for which they are looking, such as options to sort, narrow, or filter searches by record type, action or case type, date, case number, party, or specific words or phrases; and . . . offering general and advanced search and filtering options specifically within the sections of their websites that disclose adjudication materials to sort, narrow, or filter searches in the ways suggested [above].

ACUS further noted that “to the extent agencies are required to expend additional resources in implementing this recommendation, any upfront costs may be accompanied by offsetting benefits.”

**B. Statements of Policy Outside of Rulemaking**

DEA rarely issues materials that the agency would call “guidance.” DEA occasionally, however, makes statements that have the equivalent effect, in that they provide DEA’s interpretation of the CSA or of DEA’s own regulations, but are non-binding because they are not promulgated through notice and comment rulemaking.
Two examples of such statements are letters to industry and press releases. We have mentioned three such letters to industry previously in this comment: two letters expressing DEA’s interpretations of the requirements relating to “due diligence” and suspicious orders monitoring sent to registrants in 2006 and 2007, and one letter clarifying the requirement to obtain a separate listed chemical registration to handle high-concentration iodine products following the 2007 rulemaking.

More recently, in the press release announcing a settlement agreement with the drug manufacturer Mallinckrodt, DEA announced a policy interpretation: “The resolution advances the DEA’s position that controlled substance manufacturers need to go beyond ‘know your customer’ to use otherwise available company data to ‘know your customer’s customer’ to protect these potentially dangerous pharmaceuticals from getting into the wrong hands.”

HDA makes three recommendations relating to these types of statements.

First, statements expressing DEA’s interpretations can be useful to industry. As OMB has noted, “Well-designed guidance documents serve many important or even critical functions in regulatory programs. . . . Guidance documents, used properly, can channel the discretion of agency employees, increase efficiency, and enhance fairness by providing the public clear notice of the line between permissible and impermissible conduct while ensuring equal treatment of similarly situated parties.” In general, HDA members prefer written statements of DEA’s positions that are provided by headquarters to all regulated parties and DEA staff. We also strongly endorse OMB’s view that “Poorly designed or misused guidance documents can impose significant costs or limit the freedom of the public.”

Second, HDA recommends that DEA make all of its existing non-binding policy statements available at a single page of the Diversion Control Division’s website (deadiversion.usdoj.gov) so that regulated industry may more easily access and understand them. At present, the Diversion Control Division’s website does not collect these policy statements in a single location. In fact, in order to find these documents through the online search function, a registrant must already know that the documents exist. Were DEA to take this suggestion and place all existing policy statements in a single location on the website, we believe that many registrants would learn of DEA interpretations of which they previously were not aware.

Third, HDA commends to OLP and DEA the ACUS Recommendation 92-2: Agency Policy Statements, including the following points:

**Notice of nonbinding nature.** Policy statements of general applicability should make clear they are not binding. Persons affected by policy statements should be advised such policy statements may be challenged in the manner described . . . below. Agencies should also ensure, to the extent practicable, that the nonbinding nature of policy statements is communicated to all persons who apply them or advise on the basis of them, including agency staff, counsel, administrative law judges, and relevant state officials.
Procedures for challenges to policy statements. Agencies that issue policy statements should examine and, where necessary, change their formal and informal procedures, where they already exist, to allow as an additional subject requests for modification or reconsideration of such statements. . . . The procedures should not merely consist of an opportunity to challenge the applicability of the document or to request waivers or exemption from it; rather, affected persons should be afforded a fair opportunity to challenge the legality or wisdom of the document and to suggest alternative choices in an agency forum that assures adequate consideration by responsible agency officials. The opportunity should take place at or before the time the policy statement is applied to affected persons. . . . Agencies should not allow prior publication of the statement to foreclose full consideration of the positions being advanced. When a policy statement is subject to repeated challenges, agencies should consider instituting legislative rulemaking proceedings on the policy.59

In conclusion, we reiterate that we offer these comments with the goal of improving interactions between DEA and the pharmaceutical supply chain, with the overarching objective of preventing drug diversion and abuse. By working together with regulators, the entire supply chain can continue to improve its effectiveness in achieving our shared objective of stemming the opioid epidemic and preventing future occurrences. Thank you again for the opportunity to provide input into these important regulatory reform efforts. We wish you every success moving forward.

Kind regards,

John M. Gray
President and Chief Executive Officer
Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control to DEA Registrants (Sept. 27, 2006) [hereinafter 2006 Letter from Deputy Assistant Administrator].

Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control to Registrant (Dec. 27, 2007) [hereinafter 2007 Letter from Deputy Assistant Administrator].


2006 Letter from Deputy Assistant Administrator, supra note 1, at 2.


2006 Letter from Deputy Assistant Administrator, supra note 1, at 3.

Id.


See 2006 Letter from Deputy Assistant Administrator, supra note 1, at 3.

Id.

The 2006 Letter from Deputy Assistant Administrator is particularly confusing in this respect.

E.g., “ordering excessive quantities of a limited variety of controlled substances . . . while ordering few, if any, other drugs,” whether “one or more practitioners writ[e] a disproportionate share of the prescriptions for controlled substances being filled by the pharmacy,” and whether “the pharmacy charge[s] reasonable prices for controlled substances.” 2006 Letter from Deputy Assistant Administrator, supra note 1, at 3.

See also Government Accountability Office, Prescription Drugs: More DEA Information about Registrants’ Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access at 27 (June 2015) available at https://www.gao.gov/assets/680/671032.pdf [hereinafter GAO Report] (“[A]lthough DEA may not be able to provide guidance that will definitively answer the question of what constitutes a suspicious order or offer advice about which customers to ship to, DEA could, for example, provide guidance around best practices in developing suspicious orders monitoring systems.”).

2006 Letter from Deputy Assistant Administrator, supra note 1, at 3.


2006 Letter from Deputy Assistant Administrator, supra note 1, at 3.


Id. at 55478 & 55479 (“Respondent’s senior officials were, at the time of the orders at issue here, well aware of the serious problem of diversion and drug abuse, and in particular, the diversion and abuse of oxycodone, then existing in the State of Florida.”).


21 C.F.R. § 1303.31(a).

Id. § 1308.41.


While no order form is required when registered collectors transfer collected controlled substances to a reverse distributor or distributor (21 C.F.R. § 1305.03(f)), no exemption has been granted for similar transfers of controlled substances from a dispenser’s inventory for disposal.


Masters slip op., supra note 5, at 23.

The Court of Appeals declined to opine on “DEA’s statutory authority to use an adjudication to modify a rule enacted through notice and comment.” Id. at 18.


DEA also issues guidance statements in presentations to industry that are then posted on the Diversion Control Division’s website. For instance, the “Suggested Questions a Distributor should ask prior to shipping controlled substances,” supra note 7, was presented at an industry conference. The recommendations within this section apply equally to those types of statements by the agency.

See 2006 Letter from Deputy Assistant Administrator, supra note 1, and 2007 Letter from Deputy Assistant Administrator, supra note 2.

Letter from Mark Caverly, supra note 22.


Id. at 3433.

While the Diversion Control Division website has a page of “manuals,” limited information is included in each.

See also GAO Report, supra note 15, at 21 (“While DEA’s website contains information and links for specific guidance, tools, and conferences, if registrants are unaware that these types of resources exist, they will not know to search DEA’s website for them.”).
58 To the extent that such public statements restate binding regulatory requirements as established through informal rulemaking or formal adjudication, we recommend that DEA include a clear and direct reference to original statement, to avoid confusion.  
59 ACUS, Recommendation 92-2 at 3-4.