



Lilly USA, LLC

Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

November 28, 2022

SUBMITTED ELECTRONICALLY (<https://www.reginfo.gov/public/do/PRAMain>)

Carole Johnson
Administrator
Health Resources and Services Administration (HRSA)
Department of Health and Human Services
5600 Fishers Boulevard
Rockville, MD 20857

Maria G. Button
Director, Executive Secretariat
Health Resources and Services Administration
Department of Health and Human Services
5600 Fishers Boulevard
Rockville, MD 20857

RE: Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Enrollment and Re-Certification of Covered Entities in the 340B Drug Pricing Program, OMB Number 0915-0327—Revision

Dear Administrator Johnson and Ms. Button,

Eli Lilly and Company (Lilly) is pleased to respond to the above-captioned Information Collection Request (ICR).¹ According to the ICR, information provided in response to this collection effort will be used “[t]o ensure the ongoing responsibility to administer the 340B Program while maintaining efficiency, transparency and integrity” and to permit a “HRSA developed [] process of registration for covered entities to enable it to address specific statutory mandates.” We support these goals.

We are concerned, however, that between the June 14, 2022 ICR proposal (87 Fed. Reg. 35,983) and the October 28, 2022 ICR proposal, certain proposed changes to the enrollment, eligibility and recertification processes will, if adopted, further erode the transparency and accountability upon which HRSA’s current registration and recertification principles are based. Specifically, we are concerned that HRSA’s proposed removal of the attestation of compliance with contract pharmacy requirements by Authorizing Officials will weaken controls and accountability and will further undermine program integrity in an aspect of the program that is already replete with non-compliant conduct.

I. Authorizing Official Attestations of Compliance with Contract Pharmacy Requirements Are Minimally Burdensome and Important to Maintaining Integrity and Should Not Be Removed or Replaced by Statements on Other Documents.

In this ICR, HRSA has proposed to remove the requirement that the Authorizing Official (AO) must, in the context of (re)certification, accept responsibility for ensuring that a contract-pharmacy

¹ 87 Fed. Reg. 65,212 (Oct. 28, 2022).

arrangement is performed in “accordance with OPA requirements and guidelines.”² HRSA’s rationale for deleting this statement from the AO certification is that it is ostensibly duplicative of statements elsewhere, e.g., on the initial registration form. But as HRSA knows, a personal certification attesting to ongoing compliance is different from an initial registration instrument, as the entire purpose of re-certification is to re-examine and renew particular commitments. Moreover, it is sometimes necessary and helpful to expressly reiterate compliance commitments and to assign to an important individual personal accountability for ensuring such compliance. Lilly can think of no aspect of the currently constituted 340B program where assigning individual accountability to an AO is more significant than in the context of contract pharmacy compliance because there is no other aspect of the 340B program that is so opaque and potentially subject to misunderstanding by HRSA itself.

Over the last ten (10) months, Lilly has acquired first-hand information regarding the practices of certain covered entities and contract pharmacies that is wholly incompatible with our expectations and HRSA’s statements about how those relationships are supposed to work. Our experiences collecting claims-level detail and interacting in direct ways with contract pharmacy programs also demonstrates that the descriptions of contract pharmacy operations made by HRSA officials (under oath and elsewhere) are either inaccurate or so general as to be misleading as to the actual operations of contract pharmacy practice.

Since the purpose of an ICR is to collect information that the agency may not possess and may wish to evaluate in determining whether certain program administration documents are too burdensome or not burdensome enough, Lilly is providing this detailed information to HRSA for consideration as it seeks to evaluate the need for clear AO accountability for contract pharmacy compliance.

Below please find some information that may not be in HRSA’s current consideration set or in the administrative record supporting this ICR:

1. Contract Pharmacy Relationships Result in Multiple Covered Entities Receiving a 340B Price Concession on the Same, Single Unit of a Dispensed Covered Outpatient Drug.

HRSA may not know (as Lilly did not until recently) that multiple covered entities can—and do—claim the same individual as a “patient” of their respective institutions. This phenomenon results in multiple covered entities claiming ownership of a single prescription and then each entity seeking (and obtaining) a replenishment dose of that drug at the 340B price.

Based on claims-level detail collected by Lilly over just the last 10 months and covering just a portion of covered entities, we have identified several instances where multiple replenishment orders were tied to a single dispense. In other words, when an individual patient purchases a drug at a contract pharmacy that relies on the replenishment model, multiple contract pharmacies use algorithms to identify the patient after the fact as their covered entity’s patient, and multiple contract pharmacies can (and do) replenish that one script with more than one 340B-priced unit, even though just a single prescription was dispensed. This is a clear violation of the statute, which permits only a single sale of a covered outpatient drug to only actual patients of a covered entity. This improper—potentially fraudulent—practice results in unjust enrichment by the contract pharmacies and covered entities that profit off the spreads between the 340B price and the amounts at which drugs are purchased or reimbursed.

² *Id.* at 65,213.

2. Contract Pharmacy Relationships Frequently Result in Duplicate Discounts.

HRSA is well aware that contract pharmacy relationships result in an increased risk of statutorily prohibited duplicate discounts with Medicaid.³ In the 10 months that Lilly has been collecting claims-level detail on just a portion of covered entities' 340B purchases, we have been able to identify with greater precision the frequency of these statutory violations in the context of contract pharmacy arrangements. Specifically, for Q4 2021, Lilly identified 869 claims (10,243 units) where 340B-priced replenishment orders were being sought on claims where Medicaid had also submitted a rebate request; and as of the date of that analysis, only 475 covered entities (out of approximately 5,021 unique covered-entity IDs that use contract pharmacies) were submitting claims data. The numbers were worse for Q1 2022. At that time, Lilly identified 1,985 claims (21,019 units) where 340B-priced replenishment orders were being sought on claims where Medicaid had also submitted a rebate request; and as of the date of that analysis only 694 entities (again, of 5,021 nationwide) were submitting claims data. **A conservative extrapolation of these data across all entities that use contract pharmacies and all quarters in a year would suggest that Lilly alone is subject to approximately 57,000 unlawful duplicate-discount claims** (or about 600,000 pills or milligrams) just through contract pharmacies.⁴ The prohibition in the statute is absolute, and there is no room in the program for any duplicate discount violations whatsoever.

3. Contract Pharmacy Relationships Increase Diversion.

Even though the term “patient” is expressly included in the 340B statute, where it functions to limit the possible universe of 340B utilization, the term “patient” has long been subject to creative and expansive interpretations that have resulted in an environment where any transaction involving fulfillment of any prescription by any person who has ever interacted with any covered entity in any way can be defined as an eligible 340B sale. Lilly appreciates that HRSA published non-binding guidance defining this critical statutory term in 1996, but covered entities—and the cottage industry of vendors who profit from the 340B program—have drifted from that guidance and now promote an even more elastic definition of “patient” and new methods for “referral capture” of 340B prescriptions.⁵

³ See, e.g., GAO, *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* (June 2018) (discussing “identified noncompliance at contract pharmacies,” including diversion findings in HRSA audits), available at <https://www.gao.gov/assets/700/692697.pdf>; OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 (Feb. 2014), at 1-2 (“We found that contract pharmacy arrangements create complications in preventing diversion, and that covered entities are addressing these complications in different ways. . . . In some cases, these different methods lead to differing determinations of 340B eligibility across covered entities. That is, two covered entities may categorize similar prescriptions differently (i.e., 340B-eligible versus not 340B-eligible) in their contract pharmacy arrangements.”), available at <https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf>.

⁴ Assuming 1,985 claims per quarter for just the 694 entities currently submitting claims-level data, extrapolating to four quarters results in 7,910 duplicate claims per year. Multiply that by 7.2, the factor needed to nationalize the sample to 5,021 entities, and the result is 57,227 duplicate claims per year. Apply the average number of units per duplicate claim seen in the data thus far (about 10.5) and the result is 605,672 duplicate units. This is a rough estimate, but also a conservative one as the entities submitting claims are relatively small customers and this analysis assumes that volume is not growing in the 340B segment.

⁵ See, *Genesis HealthCare v. Becerra*, No. 20-1701 (4th Cir. 2022). According to statements made by a government attorney to the 4th Circuit Court of Appeals referring to the 1996 “patient” definition guidance, “[t]his is non-binding guidance so I suppose Genesis does not have to follow it.” Recording available at <https://www.youtube.com/watch?v=4SaMISDuJMc>. Covered entities have since relaxed their own definitions of “patient” in recognition of the government’s own lax views.

One emerging practice involves so-called patient “self-referrals,” which Lilly learned about through unsolicited reporting from a concerned covered-entity pharmacist. A 340B-eligible-patient “self-referral” occurs when a patient, of his or her volition, seeks and receives services from a provider who is wholly unaffiliated with a covered entity and to whom the covered entity has made no referral. A contract pharmacy will dispense any resulting prescription and a third-party administrator (or a different vendor) will identify the patient as having an affiliation with a covered entity so that the covered entity can claim 340B pricing for the prescription that resulted from that wholly separate interaction, even though the covered entity played no role in it. We appreciate that HRSA’s own lawyers have represented in oral argument that the 1996 definition is purely advisory and that in a world where there is no “patient” definition, everyone can be a patient and diversion is effectively guaranteed. Even by those loose standards, however, the notion of “self-referrals” seems worthy of HRSA’s attention as it considers this ICR.

4. Contract Pharmacies Are Not “Agents” of Covered Entities.

HRSA and HHS have, on multiple occasions, characterized contract pharmacies as “agents” or “purchasing agents” of covered entities, and they have stressed the importance of this relationship. For example:

- In the 1996 Contract Pharmacy Guidance HRSA stated, “[t]he contract pharmacy would **act as an agent of the covered entity**, in that it would not resell a prescription drug but rather distribute the drug on behalf of the covered entity. This situation is akin to a covered entity having its own pharmacy.”⁶
- In the December 30, 2020 HHS Advisory Opinion (which is now withdrawn), HHS’s General Counsel stated, “The notion that the legitimate transfer of drugs to contract pharmacies so that they can be dispensed to patients of the covered entity constitutes diversion not only ignores the realities of accounting, but also that the covered entity and contract pharmacy are not distinct, **but function as principal-agent.**”⁷
- In a 2022 declaration, Admiral Krista Pedley (former HRSA Administrator) described the varying “logistics of placing the replenishment order,” stating “for example, sometimes the covered entity places the order, sometimes **the contract pharmacy orders it as a purchasing agent of the covered entity**, sometimes the order is submitted by the TPA.”⁸

Yet, despite these repeated assertions and clear expectations by HRSA and HHS that an “agency” relationship exists, **the evidence shows that contract pharmacies generally are not agents** of covered entities. Multiple publicly available contract pharmacy agreements (indeed every single one we could locate) demonstrate that most contract pharmacy arrangements are the opposite of agency arrangements. The contract pharmacies are expressly and deliberately established as mere “independent contractors,” each party is free to operate independently of the other, and each accepts responsibility only for its own conduct. For example:

⁶ 61 Fed. Reg. 43,550 (Aug. 23, 1996).

⁷ Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program (December 30, 2020) (withdrawn) at 6.

⁸ Declaration of Krista M. Pedley (June 16, 2021) at 3. Docket No. 125-2. *Eli Lilly and Company v. Becerra*, Case 1:21-cv-00081 (S.D. IN).

- CVS's agreements actively disclaim an agency relationship, stating: "**Independent Contractors**. The Parties to this Agreement are independent contracts, and have no other legal relationship under or in connection with this Agreement. The provisions of this Agreement do not, and are not intended to, create a partnership, joint venture, agency, or employment relationship among or between the parties."⁹
- Walgreen's standard contract pharmacy agreement states: "**Independent Contractor**. None of the provisions of this Agreement are intended to create, nor shall they be deemed or construed to create, any relationship between the parties hereto other than that of independent entities contracting solely for the purposes of effecting the provisions of this Agreement. Neither of the parties shall be construed to be the partner, co-venturer, or employee or representative of the other party."¹⁰
- ReCept, a smaller independent contract pharmacy, has an agreement that states: "**Independent Contractor**. None of the provisions of this Agreement are intended to create, nor shall they be deemed or construed to create, any relationship between the parties hereto other than that of independent entities contracting solely for the purposes of effecting the provisions of this Agreement. Neither of the parties shall be construed to be the partner, co-venturer, or employee, or representative of the other party."¹¹
- Bon Secours Hospital, a covered entity's template agreement also states: "Relationship Between Parties. Pharmacy shall perform all professional and other services under the terms of this Agreement as an **independent contractor**."¹²

It is abundantly clear that an agency relationship, if it ever exists between covered entities and contract pharmacies, is the exception and not the rule, and HRSA's expectation of an agency relationship—seemingly central to the very premise of allowing contract pharmacies to order 340B drugs—is being routinely flouted.

5. Contract Pharmacy Relationships May Not Result in Covered Entities Ever Taking Title to a Covered Outpatient Drug.

HRSA and HHS appear to think that covered entities take and maintain title to 340B-priced products. For example:

⁹ Pharmacy Services Agreement Between the County of Monterey and CVS Pharmacy, Inc.

<https://monterey.legistar.com/LegislationDetail.aspx?ID=4147774&GUID=EE300736-E50B-4D8B-90B0-6E9C76D79B5C&Options=ID|Text|&Search=cv> (Section 26 at 9).

¹⁰ 340B Contract Pharmacy Services Agreement Between the County of Monterey and Walgreen Co. <https://monterey.legistar.com/LegislationDetail.aspx?ID=5522598&GUID=8FC2DD5D-729C-40DC-920F-A1E2D2B7505B&Options=ID|Text|&Search=walgreen> (Section 8.10 at 13).

¹¹ 340B Contract Pharmacy Services Agreement Between ReCept Pharmacy and Dallas County, Texas. <https://dallascounty.civicweb.net/document/22291/340B%20Contract%20Pharmacy%20Services%20Agreement%20-%20ReC.pdf?handle=14153A9B5B144FA481F57285DBE67709> (see, Section 8.10 at 14, clarifying that the contract pharmacy is an "Independent Contractor")

¹² Bon Secours Contract With The Contract Pharmacy 340B Contract Pharmacy Services Agreement at 11 (Section 14 stating that the contract pharmacy will be an "independent contractor" not an agent) available at <https://dbm.maryland.gov/contracts/Documents/ContractLibrary/DPSCS/PharmacyServices/DPSCS-Q0016025-AttachmentZ-1.pdf>.

- In the 1996 Contract Pharmacy Guidance, HRSA stated, “[b]ecause the covered entity purchases the drug, **retaining title**, and directs shipment to its contractor, it retains responsibility for the drug,” and HRSA noted that “it is clearly stated in the guidelines that **the covered entity must purchase the drug (not the contractor), which would give to the covered entity title to and responsibility for the drug**”¹³
- In 2010 Contract Pharmacy Guidance, HRSA stated, “The following are **essential** elements to address in contract pharmacy arrangements: (a) **The covered entity will purchase the drug, maintain title to the drug** and assume responsibility for establishing its price....”¹⁴
- In the 2020 HHS Advisory Opinion, HHS stated, “Here, **as we understand it**, the medications at issue are sold by the manufacturer to the covered entity; **the covered entity takes title** and the covered entity pays the manufacturer either directly or through the manufacturer’s distributor. In either event, the arrangement between the manufacturer and covered entity is a straightforward ‘sale’ which ‘consists of the passing of title from the seller [drug manufacturer] to the buyer [covered entity] for a price.’ Uniform Commercial Code (U.C.C.) § 2-106.1. A ‘buyer’ is, by definition, a ‘purchaser.’ BLACK’S LAW DICTIONARY (11th ed. 2019) (defining ‘buyer’ as ‘[s]omeone who makes a purchase’). The situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant. *See* U.C.C. § 2-401(2) (‘Unless otherwise explicitly agreed title passes to the buyer at the time and place at which the seller completes his performance with reference to the physical delivery of the goods ...’).”¹⁵

Taking and maintaining title to product is an important control necessary to ensure that covered entities can reasonably administer compliance controls over 340B-priced products. Unfortunately, there is ample publicly available evidence that confirms covered entities do not retain title to 340B-discounted drugs in contract-pharmacy arrangements. For example, the 340B Contract Pharmacy Services Agreement between Walgreen Co. and the Monterey County Department of Health specifies explicitly that **the contract pharmacy obtains title** to 340B-discounted drugs upon delivery from the supplier (which may be a manufacturer or wholesaler).¹⁶ Indeed, this kind of title provision is common in contracts between covered entities and contract pharmacies.¹⁷ In the case where a manufacturer and wholesaler specify contract terms where title passes from the manufacturer at the destination point (F.O.B. Destination), the covered entity may never even touch title. And where the

¹³ 61 Fed. Reg. 46553 (Aug. 23, 1996).

¹⁴ 75 Fed. Reg. 10277 (Mar. 5, 1996).

¹⁵ Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program (December 30, 2020) (withdrawn) at 3.

¹⁶ *See, County of Monterey & Walgreen Co. 340B Contract Pharmacy Services Agreement* at 5, <https://monterey.legistar.com/LegislationDetail.aspx?ID=5522598&GUID=8FC2DD5D-729C-40DC-920F-A1E2D2B7505B&Options=ID|Text|&Search=walgreen> (“Covered entity will hold title to replacement 340B Drugs from the time Supplier fills an order from Walgreens made on behalf of the Covered Entity until the time that Walgreens takes delivery of such drugs at the applicable CIRS or Retail Pharmacy, at which time title shall pass to Walgreens.”)

¹⁷ *See, Dallas County & ReCept Pharmacy 340B Contract Pharmacy Services Agreement* at 5, <https://dallascounty.civicweb.net/document/22291/340B%20Contract%20Pharmacy%20Services%20Agreement%20-%20ReC.pdf> (“County shall purchase 340B Drugs through a written contract with the Supplier and shall hold title to such drugs from the time the Supplier fills the order from ReCept [(the contract pharmacy)] made on behalf of the County until the time that ReCept takes delivery of the drugs.”)

manufacturer conveys title at the shipping point (F.O.B. Origin), the covered entity would only have glancing, legally fictitious title while the product is on the delivery truck. Indeed, the fact that two distinct and unrelated entities can claim ownership of the same prescription (as described above) further demonstrates how fictitious the claims to “title” are in the context of the replenishment model.

6. Contract Pharmacy Replenishment Transactions Rely on Unexplained, Undefined, and Largely Ungoverned Practices and Concepts Nowhere Described in Statute or By HRSA Guidance.

HRSA has described the contract pharmacy replenishment model in simplistic terms that bear no relationship to many—perhaps most—forms of replenishment transactions that occur. According to HRSA’s sworn declarations, replenishment involves a simple three-step process:¹⁸

- “First, a contract pharmacy dispenses a certain drug in a certain amount—say, 90 tablets of Amoxicillin—to a patient (the dispense). That patient may present a prescription to the pharmacy, or the dispense may result from ‘e-prescribing,’ whereby the covered entity directly transmits the prescription to the pharmacy. Either way, the dispensed drug comes from the contract pharmacy’s own inventory.”
- “Second, the 340B software notifies the covered entity that it may place a replenishment order for the drug in question—90 tablets of Amoxicillin—under the covered entity’s 340B account with the relevant wholesaler.”
- “Third and finally, the drug in question—90 tablets of Amoxicillin—is shipped to the contract pharmacy, where it is placed on the shelf, becomes ‘neutral inventory,’ and may be dispensed to any subsequent patient.”

HRSA may not realize, however, that this is a highly stylized and misleadingly simplistic description of what happens in practice. Based on evidence Lilly has obtained, HRSA’s description does not describe other “layers” of transactions that are routinely employed but appear nowhere in HRSA’s contemplation set (or descriptions). These include:

- Post Hoc Claims-Harvesting Practices: Admiral Pedley’s description above suggests that there are only two methods for a contract pharmacy to identify the 340B prescription—either a patient shows up with a written prescription (clearly identifying the covered-entity provider) or via “e-prescribing” where “the covered entity directly transmits the prescription to the pharmacy.” This description suggests a tight and clean nexus between the patient and the institution. Based on our experience, that is not how claims are identified. Instead, third-party administrators “harvest” claims and attempt to match patients to covered entities and providers. This is done weeks or months in arrears. The vendors that offer the IT solutions market their abilities to identify more 340B claims via this process. This concept is nowhere described by HRSA or Admiral Pedley and has no resemblance to the written prescription or e-prescribing methods described above.

¹⁸ Pedley Decl. at 2-3.

- Contract Pharmacy Machine Logic Tests for the Most Profitable Outcomes. Deeming Someone a 340B Patient Only When Most Profitable: It was also surprising to Lilly to learn that Walgreens, the largest contract pharmacy chain, does not follow the procedure HRSA outlined in its court declarations. We have learned that several contract pharmacies, including Walgreens, claimed that they could not identify a 340B transaction until or unless a wholesaler gave them access to the 340B price. We further learned the reason: because their proprietary algorithms run various profitability scenarios on the claims that have been harvested and assign a patient's 340B status if that is the most financially beneficial outcome to the pharmacy or covered entity. Again, this concept is nowhere described or alluded to in Admiral Pedley's Declaration, and we do not believe HRSA would or should endorse it.
- Central-Fill Pharmacies and "Shared Accumulators": Another feature common in the contract pharmacy environment, but nowhere described or contemplated in Admiral Pedley's declaration, is that sometimes contract pharmacies *themselves* use *another* contract pharmacy. These nested relationships frustrate transparency and accountability and are very difficult to manage. Covered entities call these "central fill" pharmacies. This means that, contrary to Admiral Pedley's description, the drug is NOT "shipped to the contract pharmacy, where it is placed on the shelf, becomes 'neutral inventory,' and may be dispensed to any subsequent patient," but is, instead, shipped to a pharmacy that did not dispense the original prescription which may then forward it to the original dispense pharmacy or – and this was new to us – may forward that replenishment order shipment to a different pharmacy entirely. When we asked why or how this made sense, we were informed that there is something called a "shared accumulator" which apparently allows different contract pharmacies to trade amongst themselves accumulated 340B eligible prescriptions. It is not clear how this is anything other than impermissible statutory diversion. Regardless, it is not described or alluded to in Admiral Pedley's declaration.

7. Contract Pharmacy Relationships Exist Nowhere Else in the Drug Distribution System.

Finally, we believe that HRSA should retain AO attestations of compliance regarding contract pharmacy arrangements because these types of relationships exist nowhere else in the drug delivery and payment system and are wholly unique to the 340B program. Manufacturers and wholesalers do not have systems or procedures in place to ensure that compliance routinely occurs in the context of contract pharmacy arrangements because—outside of the 340B program—these arrangements simply do not exist and are not entered into willingly by manufacturers. HRSA may be under the misimpression that contract pharmacy relationships are commonplace and that the exotic, highly stylized practice of using a "replenishment model" is common. Let us assure you, they are not. Accordingly, manufacturers are at the mercy of covered entities when it comes to ensuring these relationships have integrity, have transparency, and are faithful to the statute—all the more reason why HRSA should maintain the accountability associated with an AO certification.

II. Conclusion

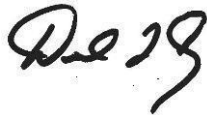
As HRSA considers in this ICR whether to strengthen or relax the compliance "burden" on covered entities and their Authorizing Officials, we hope it acknowledges and incorporates the information described above. In summary:

- Contrary to HRSA and HHS guidance and expectations, **most contract pharmacies are not “agents”** but rather independent contractors—undermining one of the few compliance controls in the contract pharmacy system;
- Contrary to HRSA and HHS’s clear direction, understanding, and expectations, **most contract pharmacy relationships do not result in a covered entity taking or maintaining title** in any meaningful way—undermining another mechanism for enhancing compliance;
- Despite HRSA guidance and enforcement efforts, **covered entities adopt varied and expansive definitions of “patient,” thus rendering any controls against diversion illusory**;
- In violation of unambiguous statutory provisions, **covered entities and contract pharmacies frequently seek or cause duplicate 340B discounts** on claims subject to Medicaid rebate requests;
- In the absence of HRSA guidance (and perhaps knowledge), **multiple 340B discounts can be (and are) collected on a single dispensed prescription**; and
- **Contract pharmacy arrangements are unique, exotic, and subject to all manner of ungoverned relationships and concepts found nowhere in the 340B statute or HRSA guidance** (e.g., central fill pharmacies, patient “self-referrals,” “shared accumulators,” etc.) and neither manufacturers nor HRSA has the ability or resources to monitor the patchwork of practices, some of which doubtlessly increase the risk of noncompliance, because these relationships are not common in the healthcare delivery system nor are they disclosed to manufacturers or HRSA.

It is against this opaque and confusing backdrop that HRSA must reconsider the compliance-certification language proposed in the ICR. HRSA should not remove the AO attestation, which, however limited, is one of the few compliance safeguards that currently exists.

We appreciate the opportunity to comment on this ICR and are available to answer any questions or address any concerns raised by this letter.

Sincerely,



Derek L. Asay
Senior Vice President, Government Strategy, Lilly USA