SENIOR CARE PHARMACY COALITION

1700 PENNSYLVANIA AVENUE, NW, SUITE 200, WASHINGTON, DC 20006

June 12, 2020

Via Electronic Transmission

The Honorable Alex Azar
Secretary, United States Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Insulin Pens - Regulatory Conflict

Dear Secretary Azar:

We are writing to bring to your attention conflicting legal and regulatory requirements and interpretations from the Food and Drug Administration (FDA) and the Department of Health and Human Services Office of Inspector General (OIG) concerning insulin pens, and the significant implications for compliance with Medicare and Medicaid Requirements of Participation for nursing homes and for government-sponsored prescription drug payment programs. Absent clear, consistent and coordinated instruction from multiple government agencies, patients in nursing homes and other LTC facilities are at medical risk, the LTC facilities in which they reside may be unable to comply with applicable regulations and the long-term care ("LTC") pharmacies that dispense their medications face potential sanction and adverse financial impact regardless of good faith compliance efforts.[1]

The Senior Care Pharmacy Coalition (SCPC) represents 400 LTC pharmacies across the country. Our members serve more than 850,000 people every day in the nation's nursing homes and other LTC facilities. Many of these patients rely on insulin to treat diabetes, and characteristics unique to medication management and administration for patients in nursing homes and other LTC facilities often warrant specific consideration as regulatory agencies develop and revise policies.

Issue: Drug manufacturers package insulin pens in multi-pen boxes, typically five pens to a box. The typical pen contains multiple doses of insulin and can be used over several weeks. Thus, depending on the patient, an entire box of pens may be necessary to provide a 30-day supply of medication, while for other patients only one pen may be needed. The OIG through enforcement

[1] Under federal law, long-term care facilities are defined as Skilled Nursing Facilities (SNFs)(facilities that provide minimum levels of care by registered nurses for Medicare beneficiaries under Part A and Medicare Advantage), Nursing Facilities (NFs)(facilities that provide minimum levels of care from registered nurses, licensed practical nurses and nursing assistants for Medicaid beneficiaries) and Intermediate Care Facilities (ICFs)(facilities that provide minimum levels of nursing and other services to Medicaid beneficiaries who have various physical and mental disabilities). 42 U.S.C. § 1395i-3, 1396r.

activity has interpreted applicable law to prohibit routine dispensing of unbroken boxes, and has accused pharmacies dispensing whole unopened boxes, rather than individual pens, of fraud.[2] In direct conflict, last year, the FDA requested that insulin manufacturers submit a safety-related supplemental application to update their labels to state that insulin pens should be dispensed "in the original sealed carton."[3] Payers, particularly Part D Prescription Drug Plans (PDPs), have used both interpretations to deny pharmacy claims for payment, and state Medicaid programs routinely refuse to provide prior approval or pay for dispensing insulin pens by the box, and payers have established conflicting policies that in some cases may inadvertently expose LTC pharmacies to compliance concerns. We request your assistance to reconcile this conflict between agencies within your Department.

The regulatory conflict began in January 2019, when the OIG announced settlement of a case with Walgreen's based on the premise that dispensing insulin pens in manufacturer boxes rather than as individual insulin pens, constitutes fraud under the Medicare, Medicaid, and other federal laws. As a result, PDPs in the Part D program and the Pharmacy Benefits Managers (PBMs) that administer such plans began recouping payments made to pharmacies under the Part D program if a pharmacy did not dispense individual pens. The basis for these recoupments is that pharmacies were alleged to be dispensing unnecessary amounts of insulin by dispensing insulin pens in manufacturer boxes.

Ten months later, in November 2019, the FDA issued updated labeling requirements for many insulin products – including insulin pens – that specifically prohibit "breaking" a box of pens to dispense in individual units. An example of one such label may be found here – particularly §16.2, which states: "[d]ispense ***in the original sealed carton*** with the enclosed Instructions for Use" (emphasis supplied). Shortly after the FDA made this announcement, PDPs and PBMs began recouping Part D payments to pharmacies that dispensed individual pens. The basis was that pharmacies violate the FDA requirement *unless* insulin pens are dispensed in manufacturer boxes.

More recently, LTC pharmacies have received conflicting guidance from various PBMs on behalf of multiple payers. In at least one case, those instructions may inadvertently increase the risk of exposure to fraud claims, since they apparently instruct LTC pharmacies to bill for 30-day supplies every thirty days, while charging for a 50-day supply every two months. Attached is a notice PerformRx sent to LTC pharmacies in late May 2020 describing this PBM "rule." By contrast, another PBM, Abarca, instructed pharmacies to "process the lowest available package currently

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[2] https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-2692-million-recovery-walgreens-two-civil-healthcare.

[3] See https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/018780Orig1s175,%20s176ltr.pdf; https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/021081Orig1s073,%20s074;%20021629Orig1s039,%20s040;%20206538Orig1s013,%20s014ltr.pdf; https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/020986Orig1s090,%20s091;%20021810Orig1s018,%20s019;%20021172Orig1s071,%20s072ltr.pdf; https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020986s090s091lbl.pdf; and https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021081s073s074lbl.pdf.

available," with override instructions under some circumstances if claims are denied and with no guarantee that such claims will be paid or that any payments made would not be subject to recoupment upon audit. This latter instruction is contrary to the OIG's position concerning fraud and is problematic for patient safety in LTC facilities.

LTC pharmacies are caught between directly conflicting regulatory regimes. If they dispense individual pens, they run afoul of FDA instruction. If they dispense multiple pens in manufacturer boxes, they risk allegations of fraud from the OIG and state Medicaid Fraud Control Units. In either case, payers have a legitimate basis to deny claims or recoup payments and may simply deny prior authorization for amounts greater than 30-day supplies such that patients would receive no medication at all. LTC pharmacies also face conflicting interpretations and payment rules among payers and PBMs, while patients may be at greater risk.

Unique LTC Clinical and Patient Care and Provider Considerations. Unique characteristics of the LTC patient population and medication management and administration in nursing homes and other LTC settings strongly counsel in favor of dispensing individual pens, while providing LTC pharmacies the discretion to dispense boxes in appropriate cases. Any comprehensive solution must acknowledge that patients in LTC facilities would be best served by such flexibility, that LTC pharmacies acting in good faith should not be subject to sanctions from either the OIG or the FDA, and that payers should assure payment provided LTC pharmacies are making dispensing decisions in good faith. We address below how insulin is used to provide some context around the issue.

Insulin must be administered through subcutaneous injection. Insulin dosing and administration vary based on the type of insulin, the amount per dose and the injection time. Dosage per administration also may vary, based on the need to replace insulin in the body that dissipates during sleep, when fasting or between meals and the need to provide coverage for carbohydrate intake or to correct for high blood sugar. In many cases, appropriate dosage requires that the patient (for self-administration) or the health care professional administering the dose (for most residents in nursing facilities) mix two types of insulin per injection.[4]

Insulin pens are sophisticated drug delivery systems that allow multiple administrations from one pen and that allow the patient or professional to titrate specific dosage amounts precisely.[5] For each administration, the pen is attached to a disposable needle and is calibrated to the necessary dosage amount. After administration, the needle is disconnected from the pen and discarded.

One pen typically contains 3 mL, or 300 units, of insulin.[6] Typical dosages are much lower than 300 units, such that one pen could represent more than a month's supply for some patients, while

[4] See https://dtc.ucsf.edu/types-of-diabetes/type1/treatment-of-type-1-diabetes/medications-and-therapies/type-1-insulin-therapy/calculating-insulin-dose/.
[5] The Johns Hopkins Guide to Diabetes, Using an Insulin Pen, available at https://www.youtube.com/watch?v=byTAEfP4Ifg.
[6] For some pens and some manufacturers, each pen contains 10 mL, but this does not appear to be in common use.

other patients might require multiple pens/month. Manufacturers package insulin pens in boxes that typically contain five pens. For most patients, five pens well exceed a one-month supply. Consequently, in most cases, a box contains insulin sufficient for several months.

Unique LTC Patient and Provider Considerations. Unique characteristics of the LTC patient population and medication management and administration in nursing homes and other LTC settings strongly counsel in favor of dispensing individual pens, while providing LTC pharmacies the discretion to dispense boxes in appropriate cases.

For patients in LTC facilities, including Part D beneficiaries, LTC pharmacies must dispense medications to patients in unit dose, patient-specific, individually labeled packaging. Since nursing staff typically must administer medications to patients, they typically place one insulin pen per patient in the facility medication (med) cart. Med carts are organized by patient based on each patient's location in and med pass protocols at the facility, which minimizes the risk of medication errors while increasing the efficiency of medication administration.

Prior to insulin pen labeling revisions, LTC pharmacies normally would open the box of pens and label and dispense each pen by individual patient, even in the case of dispensing an entire box. If the LTC pharmacy dispensed an entire box, it labeled the box and each individual pen in the box with patient-specific information. One pen - whether dispensed in the box or dispensed individually – typically would be placed in the med cart. Nursing staff would refrigerate the remainder of the pens. Whether refrigerated in the box (typical) or as individual pens (unusual), all pens as well as the box would be individually labeled by patient.

The FDA's November 2019 revised labeling guidelines, however, prevent LTC pharmacies from opening the box and dispensing individual pens. As a result, there is substantial risk that LTC facility nursing staff will be unable to determine whether an individual pen has been dispensed to a specific patient. If staff continue placing one pen in the med cart and the remainder in the refrigerator, even if they maintain the individual pen or the remainder in the original box, either the pen in the med cart or the pens in the refrigerator will not be individually labeled. In addition, in either case, the box easily could be misplaced or discarded inadvertently.[7]

Further, the absence of a patient-specific label on each pen substantially increases the risk of medication errors and the accidental use of one pen for multiple patients which increases the risk of cross-contamination. It is noteworthy that FDA's approved labeling for insulin pens clearly state that insulin pens should not be shared between patients. For example, the package insert for NovoLog, a fast-acting insulin available in pens, states:

[7] On-site labeling by the nursing staff also is not a solution. If nursing staff label each pen individually, they likely violate state pharmacy nursing practice and pharmacy practice laws, which also could subject facilities to sanction under the Medicare and Medicaid Requirements of Participation or state law and could present compliance or payment concerns for LTC pharmacies as well.

> **5 WARNINGS AND PRECAUTIONS**
>
> **5.1 Never Share a NOVOLOG FlexPen, NOVOLOG FlexTouch, PenFill Cartridge, or PenFill Cartridge Device Between Patients**
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> NOVOLOG FlexPen, NOVOLOG FlexTouch, PenFill cartridge, and PenFill cartridge devices should never be shared between patients, even if the needle is changed. Patients using NOVOLOG vials must never share needles or syringes with another person. Sharing poses a risk for transmission of blood-borne pathogens.[8]

Placing the entire box of pens in the nursing home med cart is not a solution, since at room temperature pens may only be used for 28 days. Placing the entire box in the med cart would expose facilities to sanction under the Requirements of Participation for risking drug potency, not to mention the potential risk to patient care. Labeling individual pens at the facility once the box has been opened is not a solution, since labeling by nursing or facility staff would violate state Boards of Pharmacy laws and regulations.

The situation is even more complex in LTC facilities because insulin pens often are included in emergency kits (e-kits). The contents of e-kits are highly regulated by state Boards of Pharmacy, such that more than one insulin pen may not be included in each kit. This is a particularly sensible requirement given that pens may be stored at room temperature for no longer than 28 days. If LTC pharmacies may not open manufacturer packaging, they will not be able to include insulin pens in e-kits, with obvious adverse implications for patients.[9]

Insulin pens also may be dispensed through remote dispensing equipment located on-site at LTC facilities. Remote dispensing equipment necessarily requires that pens be removed from original packaging. Remote dispensing is subject to detailed state Board of Pharmacy requirements that may conflict with a requirement that insulin pens be dispensed in original manufacturer packaging. As with e-kits, remote dispensing equipment typically includes only one insulin pen.[10]

These examples underscore the increased risk associated with mandatory dispensing of multiple insulin pens as packaged by manufacturers for patients in LTC facilities. They also underscore the aspects of this problem unique to LTC pharmacies and to patients in LTC facilities.

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[8] See Package Insert for NovoLog, available at https://medlibrary.org/lib/rx/meds/novolog-4/page/2/#i4i_warnings_precautions_id_4bc7c883-0765-44cd-8028-c744ee1c4853 (emphasis in original).

[9] We note that, in January 2017, the FDA exercised its discretion by noting that it would not enforce new repackaging guidelines in LTC facilities because those guidelines would have prevented LTC pharmacies from providing any e-kits to facilities.

[10] Considerations regarding remote dispensing equipment contributed to the FDA's exercise of enforcement discretion described in fn. 11.

Other Considerations. We have identified other concerns regarding the recent FDA labeling changes and resulting conflict with OIG's conclusion that failure to dispense individual pens constitutes fraud under Medicare Medicaid, and other federal statutes:

1. Fraud. If LTC pharmacies comply with FDA instruction, they may be subject to allegations of fraud claims under Medicare, Medicaid, and other federal healthcare programs, which could come from the OIG, state Medicaid Fraud Control Units or third-party whistleblowers. This risk is exacerbated by payer and PBM rules and instructions.

2. Payment Denial/Recoupment. As noted above, payers and PBMs have refused prior authorization, declined coverage or recouped payment based on the OIG settlement and the FDA manufacturer label revision, and recent notices to LTC pharmacies demonstrate the ongoing risk of such actions. In particular:

    - Utilization Management/Prior Approval. Given its cost, payers, and particularly state Medicaid programs, often subject insulin to prior authorization requirements to manage utilization. These payers will not authorize payment.

    - Exceeding Dispensing Limits. Some payers, particularly state Medicaid programs, impose limits on the amount of insulin that may be dispensed at a time. In some cases, dispensing 15mL of insulin, the total amount in a box of five 3 mL pens, exceeds these limits such that the payer or PBM will not authorize or approve the prescription for payment.

3. Waste. Mandatory dispensing of multiple pens in an unopened box substantially increases the likelihood that significant amounts of insulin will be wasted. Such a practice adds unnecessary costs for all payers including Medicare Part D and unnecessarily large co-pays for patients who have co-pay obligations, an expense many seniors may be unable to satisfy.

Requested Action. The obvious regulatory conflict between agencies, as well as the secondary effects concerning payment for prescription drugs, compliance with LTC facility Requirements of Participation, and compliance with Medicare Part D Manual provisions pertaining to LTC pharmacies has created an untenable situation for both patients and the LTC pharmacies that serve them. It is essential that any solution appropriately consider the unique characteristics of the LTC patient population and the specific medication management and administration concerns in nursing homes and other LTC settings described here.

We believe that these considerations are best balanced by clearly permitting LTC pharmacies to dispense individual pens while maintain discretion to dispense boxes of pens in appropriate cases. We also believe that consistent requirements and policies across all relevant agencies and divisions

within the Department are essential to assuring patient care and safety and providing LTC pharmacies with clear and consistent guidance from the federal government and the payers and PBMs with which the federal government contracts under the Medicare and Medicaid programs.

We therefore request that:

1. The Department develop a consistent set of policies across all relevant agencies and divisions within agencies (including without limitation the FDA Center for Drug Evaluation and Research Office of Medical Policy, the OIG, the Medicare Drug Benefit and C and D Data Group, the Division of Pharmacy, Disabled and Elderly Health Populations Group, Center for Medicaid, and CHIP Services, and Division of Nursing Homes, CMS Center for Clinical Standards and Safety, as well as other policy and legal entities within the Department that may be appropriate).

2. Until the Department and its various agencies implement such consistent policies, notify all relevant stakeholders (including without limitation drug manufacturers, Medicare and Medicaid payers, State Medicaid Directors and PBMs administering Medicare or Medicaid payments and LTC pharmacies) that, provided that dispensing decisions are made in good faith and in the best interest of patient care and safety, LTC pharmacies may dispense insulin pens to patients in LTC facilities either as individual pens or in unopened boxes, that doing so:

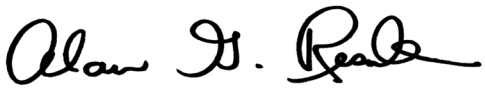
    a. Is consistent with or an exception to the FDA's revised manufacturer drug labeling.
    b. Does not constitute fraud under the Medicare and Medicaid statutes.
    c. Does not violate the Medicare Requirements of Participation for Skilled Nursing Facilities or the Medicaid Requirements of Participation for Nursing Facilities; and
    d. Is consistent with all applicable Manual provisions, policies and practices of the Medicare Part C, Medicare Part D and Medicaid programs, such that all relevant payers must process, approve, and pay for such prescriptions.

We strongly recommend that you convene all relevant agencies and divisions within those agencies and that you include appropriate stakeholders in such multi-agency/division efforts to assure consistent and effective policies across the Department. SCPC would welcome the opportunity to participate in such discussions.[11]

[11] http://www.ncpa.co/pdf/ASCP-SCPC-NCPA-Group-Letter-to-FDA.pdf. It is clear that no individual agency or division has the authority to establish such consistent policies. SCPC has had constructive interchange with the Medicare Part D program concerning these issues and has participated in a multi-stakeholder group that has spearheaded discussion of these issues with the FDA and with two insulin pen manufacturers. A copy of the joint letter from SCPC, the American Society of Consultant Pharmacists and the National Community Pharmacists Association may be found at http://www.ncpa.co/pdf/ASCP-SCPC-NCPA-Group-Letter-to-FDA.pdf. All of these discussions, while cordial, underscore the fact that neither the FDA nor the Part D program has the authority to address all aspects of the problem and that the manufacturers are unlikely to make changes sufficient to address the issues effectively.

Thank you for your consideration of this request.

Respectfully yours,



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Attachments (2)

cc: Amy Larrick, Director, Medicare Drug Benefit and C and D Data Group,
Centers for Medicare & Medicaid Services

Evan Shulman, Director, Division of Nursing Homes, Quality and Safety Oversight Group,
Centers for Medicare & Medicaid Services

Gregory Demske, Chief Counsel to the Inspector General

Anna Abram, Deputy Commissioner for Policy, Legislation, and International Affairs,
U.S. Food and Drug Administration

Jacqueline Corrigan-Curay, J.D., M.D., Director, Center for Drug Evaluation and Research
Office of Medical Policy, U.S. Food and Drug Administration

John Coster, Director, Division of Pharmacy, Disabled and Elderly Health Populations
Group, Center for Medicaid and CHIP Services

PERFORMRx℠

PerformRx
300 Stevens Drive
Philadelphia, PA 19113-1570
www.performrx.com

May 14, 2020

PerformRx Network Pharmacy

To Whom It May Concern:

FDA approved updates to the labeling of insulin pens to clarify that they should only be dispensed in the original sealed carton with the enclosed instructions for use. Nearly all insulin pen manufacturers boxes now have this same updated product labeling. As such, our pharmacies can and will only dispense full boxes of these products, in accordance with the product labeling.

We understand that many insurers day supply limit is only 30 days. We recommend that if an insulin box day supply would last 60 days then the pharmacy should not fill the medicine before 60 days. For example, a day supply for a box is 60 days, however, the insurance will only pay for a 30 days supply. The pharmacy should enter 30 days in the computer and do not dispense the next fill until 60 days.

Your cooperation and prompt attention is very much appreciated. If you have any questions, please contact our PerformRx Pharmacy Audit Department at **PharmacyAudit@PerformRx.com.**

Sincerely,

Monica Sikka

Monica Sikka
Pharmacy Network Auditor

THP
TRUSTED HEALTH PLAN
DISTRICT OF COLUMBIA

ABARCA

To: Abarca Health Pharmacy Network
From: Pharmacy Partnerships Department
Subject: Accurate Billing for Insulin Pens
Date: 5/29/2020

Dear Pharmacy Provider:

We would like to inform you about a change in the way we process claims for insulin pens. The Federal Food and Drug Administration (FDA) has asked pharmaceutical companies that manufacture these types of drugs to update the information contained in the package insert indicating that those packages must be dispensed with its instructions for use and in their original sealed packaging.

"Dispense in the original sealed carton with the enclosed Instructions for Use"

This FDA instruction will change the way these claims must be processed. For this reason, we want to clarify the following:

- Pharmacies may process the smallest available package currently available on the market (15 ml; 5 pens 3 mL) for the correct day supply based on the instructions provided by the physician on the prescription.
- **As Directed**, or any indication similar to this, will not be accepted to process the claims.
- The pharmacy is responsible to correctly process the amount of medication and days' supply based on the indications in the prescription.
- If you receive a rejection for one of the following reasons:
    - High Cost
    - Days' Supply greater that ninety (90)

  In such cases please contact our Call Center to start with the corresponding evaluation process.
- **Important**, when processing a claim, you must select the NDC that represents the total package quantity you are dispensing to the beneficiary.
- This change will be effective starting **June 1st, 2020**.

If you have any other questions or need assistance feel free to contact Abarca Health Pharmacy **Call Center at 1-855-831-3593**.

Please remember that you can access this and other communications through our Operational Portal at https://abarca.darwinrx.com/operational/.

Best Regards,

Pharmacy Partnership Department