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July 23, 2021

Via Electronic Submission (www.regulations.gov)

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
US Department of Labor
ATTN: Request for Information Regarding Reporting on
Pharmacy Benefits and Prescription Drug Costs
200 Constitution Avenue, NW, Room N-5653
Washington, DC 20210

RE: Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs; CMS-9905-NC

To Whom it May Concern:

The Senior Care Pharmacy Coalition (SCPC) appreciates the opportunity to comment on the *Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs;* CMS-9905-NC (RIN: 0938-AU66, 1210-AC07, 1545-BQ10 and 3206-AO2), 86 Fed. Reg. 32813 (June 23, 2021) (the "RFI"). The RFI seeks information on a number of questions related to the collection of commercial health insurance plan information pursuant to § 204 of the Consolidated Appropriations Act of 2021. Given the relevance of these questions to long-term care (LTC) pharmacies SCPC offers comments on several of the questions posed. We repeat the specific questions on which SCPC comments below for ease of review.

SCPC is the only Washington-based organization exclusively representing the interests of LTC pharmacies. SCPC represents 75% of all independent LTC pharmacies. Every day, our members operate in all 50 states and currently serve 850,000 residents in LTC facilities and related settings. Our members provide prescription drugs, wrap-around patient care services related to pharmacy management and utilization, and other specialized services both to seniors and younger disabled adults who need long-term services and supports (LTSS).

LTC Pharmacy Context

Because the RFI asks directly for a definition of pharmacy, we begin by addressing the nature of LTC pharmacies, key distinctions from retail, mail order, or specialty pharmacies (all of which, unlike LTC pharmacies, the RFI seeks to define). LTC pharmacies serve patients in skilled nursing facilities (SNFs), nursing facilities (NFs), assisted living communities (ALCs), congregate living

settings and at home. LTC pharmacies differ substantially from retail and mail order pharmacies.[1] Two aspects of these differences are especially pertinent to our responses to the RFI:

1. **Individuals who need LTC are more clinically complex, are less able to perform daily activities, and take significantly more prescription medications.** The complexity of LTC patients distinguishes LTC pharmacy from retail pharmacy, and underscores the value LTC pharmacies deliver through their services to patients. The typical LTC facility resident is a woman in a nursing facility (SNF) who suffers from four or more chronic conditions, multiple impairments in activities of daily living and instrumental activities of daily living, is cognitively impaired, and takes 12 prescription drugs each month.

   Individuals who need LTC are nearly three times as likely to be admitted to the hospital or visit an emergency department than the general population. The annual health care costs for an individual with LTC needs are more than three times those of an individual who does not need LTC, and individual prescription drug costs are almost double that of the general population. As a result, LTC pharmacy services – not simply dispensing medications – are crucial to the quality of care for patients and increasingly important in preventing adverse events like re-hospitalizations, patient falls, polypharmacy complications, medication-induced dementia, and other adverse drug reactions. LTC pharmacies provide specialized pharmacy services, thereby improving the quality of care and reducing Medicare expenditures.

2. **LTC pharmacies have extensive and extended clinical responsibilities to patients**. The clinical responsibility of retail pharmacies ends when the patient leaves the pharmacy with a prescription. The clinical responsibility of LTC pharmacies is more expansive, from the time the pharmacy receives a prescription through the patient's transition from a LTC facility to home or another setting is complete. LTC pharmacies, unlike retail or mail order pharmacies, provide not only prescription medications but also an array of patient care services and related specialized services. These services are designed to improve outcomes, avoid adverse

[1] Specialty pharmacies originally were created to dispense expensive drugs that required special handling and treatment, primarily because many retail pharmacies lacked the expertise to manage such medications effectively. LTC pharmacies, however, generally do have the expertise to manage these medications effectively and in some cases dispense "specialty" drugs to residents in LTC facilities. The major obstacle to LTC pharmacies providing most specialty drugs to residents are limitations and payment differentials insurers and PBMs impose which make it economically untenable for LTC pharmacies to obtain specialty drugs cost effectively.

drug interactions, assure medication adherence, minimize unnecessary drug utilization, and streamline packaging and delivery to ensure product safety and improve medication administration.

LTC pharmacy services are crucial to patient care, particularly given the medical complexity of these patients. Key clinical, patient care, and specialized services that distinguish LTC pharmacies from retail (or mail order) pharmacies include:

- Direct and ongoing consultation with patients and their families.
- Direct and ongoing training and contact with facility nursing staff.
- Pharmacist availability to patients to provide medication and patient care services 24/7/365 (even more important during COVID-19 in order to acquire and begin new medications for infected patients immediately).
- Direct placement of peripherally inserted central catheters and insertion of Midline and PICC lines.
- Federally mandated medication therapy management for Part D Plans, including Comprehensive Medication Reviews and Targeted Medication Reviews.
- Ongoing and detailed drug regimen reviews and drug utilization reviews.
- Antibiotic stewardship and infection control.
- Extensive controlled substance monitoring to reduce drug diversion potential in facilities.
- Staff and resident education programs; and
- Discharge consulting services to ensure proper medication management to reduce unnecessary hospital readmissions.

A related aspect of LTC pharmacy responsibility concerns various specialized services. LTC pharmacies must dispense medications on a unit dose basis in compliance packaging. Packaging must be uniform for all residents in a facility; otherwise, it would be much more difficult for nursing and other staff at facilities to pass medications to residents. The result would be more medication errors and inferior outcomes for patients. Retail pharmacies, by contrast, have no such responsibilities.

LTC pharmacies must provide clinical, patient care, and specialized services 24/7/365. Depending on the medication and the patient's condition, LTC pharmacies may be required to deliver a prescription drug within two hours of its receipt. The implications are especially noteworthy since LTC pharmacies are not co-located with LTC facilities. Rather, LTC pharmacies typically serve residents in many facilities in a geographic region.

Response to RFI

We focus on seven specific questions posed in the RFI because they are most relevant to the LTC patient population and the LTC pharmacies that serve them. For convenience, we reprint verbatim the questions to which we respond. Our overarching recommendation, however, is that the Departments collect information specific to the LTC pharmacy market for use, conduct analyses and issue reports specific to the LTC pharmacy market, particularly given the substantial differences between individuals who need LTC and the general population, as well as the substantial differences between LTC pharmacies and retail or mail order pharmacies.

Question 2. What considerations should the Departments and OPM take into account in defining the term ''pharmacy''? Are there different considerations for retail pharmacies versus mail order or specialty pharmacies? Are there different considerations for prescription drugs dispensed in an inpatient, outpatient, office, home, or other setting?

Answer: We urge the Departments and OPM to define the various types of pharmacies explicitly, to define LTC pharmacies distinctly from other types of pharmacies (e.g., retail, mail order, and specialty), and to collect, analyze, and report data and information specific to individuals who need LTC and specific to LTC pharmacies.

As noted above, LTC pharmacies are distinct from other types of pharmacies. They have far more extensive clinical and patient care responsibilities, must provide an array of specialized services, and maintain clinical and patient care relationships with patients over extended periods. Consequently, it is important that the Departments and OPM establish a distinct definition of LTC pharmacy.

In recognition of the expanded responsibilities LTC pharmacies must meet, payers typically provide enhanced dispensing fees to LTC pharmacies. The Medicare Part D program requires that Prescription Drug Plans (PDPs) assure network adequacy of LTC pharmacies separate from network adequacy of retail pharmacies. The Part D Manual enumerates 10 criteria that a pharmacy must satisfy to be eligible to participate in a Part D network as a LTC pharmacy. Part D requires that PDPs pay an enhanced dispensing fee to LTC pharmacies providing prescription drugs and related services to beneficiaries living in SNFs and allows PDPs to pay such fees for Part D beneficiaries who need LTC residing in other settings (e.g., senior living communities or at home).

Unfortunately, there is no federal statutory or regulatory definition of LTC pharmacy, which regularly precipitates conflicts between regulatory agencies and legislative proposals that are

sensible for the general population served by retail and mail order pharmacies but that could undermine care for individuals with LTC needs residing in LTC facilities. You may learn more about these challenges here.

We therefore recommend that the Departments and OPM adopt the following definition of LTC pharmacy:

> "LONG-TERM CARE PHARMACY" means a pharmacy licensed under applicable state law that is able to provide enhanced pharmacy and clinical services to individuals who require enhanced medication services.
> "ENHANCED PHARMACY AND CLINICAL SERVICES" include:
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> 1. Medications dispensed pursuant to a prescription or chart order in specialized packaging which shall include unit of use packaging, unit dose packaging, single use containers, packaging from remote automated dispensing technology, or other packaging required;
> 2. Drug utilization review to identify potential adverse drug reactions and inappropriate drug usage;
> 3. Medication reconciliation services at the transition of care and other necessary clinical management and medication services;
> 4. Timely medication delivery 24 hours a day, 7 days a week;
> 5. Pharmacist on-call availability to provider dispensing and clinical services 24 hours a day, 7 days a week; and
> 6. Emergency supplies of medication as permitted by law and as required, including emergency kits or remote automated dispensing technology at a facility.
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> "INDIVIDUALS REQUIRING ENHANCED MEDICATION SERVICES" means an individual who has one or more comorbid and medically complex chronic conditions that are life-threatening or significantly limit overall health or function, pose a high risk of hospitalization or other adverse health outcomes, and require enhanced pharmacy and clinical services.

This definition is based on the LTC pharmacy criteria from the Medicare Part D Manual, which would reduce the likelihood of conflicts between regulatory agencies and minimize the occurrence of well-intentioned but overly broad legislative proposals.[2] This definition also

[2] The definition also is substantially similar to , the Long-Term Care Pharmacy Definition Act of 2021 (S. 1574) which is pending in the Senate.

would allow the Departments and OPM to obtain information specific to LTC pharmacies. We therefore urge that the Departments and OPM: (1) adopt an identical definition of LTC pharmacy for purposes of the RFI; (2) collect information specific to the manner in which insurers cover and manage drugs dispensed to individuals who need LTC; (3) collect information specific to LTC pharmacies; and (4) separately analyze and publicly report information specific to LTC pharmacies.

Question 3. What considerations should the Departments and OPM take into account in defining the term ''prescription drug''? Should prescription drugs be identified by National Drug Codes (NDCs)? Are there other prescription drug classification systems that should be considered, such as the first nine digits of the NDC, the RxNorm Concept Unique Identifier (RxCUI), or the United States Pharmacopeia Drug Classification (USP–DC)? How does the choice of prescription drug classification influence plan and issuer operational costs?

Answer: SCPC urges the Departments and OPM to define prescription drugs by their 11-digit National Drug Codes (NDC) and strongly recommends against using RxNorm or USP-DC to collect information. The complexity of today's prescription drug market is reflected in the numerous different payment arrangements that could apply to a single prescription drug, depending on dose and quantity differences. To collect the appropriately granular level of information to be able to report to the public, the Departments and OPM should collect information at the NDC-11 level.

We further strongly recommend against collecting information using the RxNorm or USP-DC levels, as they will not provide the needed level of detail and will prevent the Departments and OPM from making meaningful findings or providing useful reports to the public about the aggregate data. For example, the USP-DC provides only the highest-level information about unfortunately broad therapeutic classes, self-identified by the USP in one of its several unique "therapeutic class" documents. The USP-DC conflicts with the USP Model Medicare Guidelines (USP-MMG), another so-called USP formulary. These formularies combined generic and brand name drugs into single "classes," which will obscure the different payment for and treatment of these different types of products when reported to the Departments and OPM, rendering the resultant analyses and reports far less useful in meeting the objectives of the underlying statutory provision. Therefore, the Departments and OPM should refrain from adopting these conflicting and high-level therapeutic class dictionaries as reference tools for the plan reporting requirements. Instead, the appropriate level at which to collect the data is the NDC-11.

Question 4: Should there be different definitions of ''prescription drug'' for different elements of the PHS Act section 2799A–10, ERISA section 725, and Code section 9825 data collection, such as the 9-digit NDC for identifying the 25 drugs with the highest rebates and the RxCUI for identifying the 50 most costly drugs? What classification systems do plans and issuers currently use for internal needs and compliance with reporting requirements other than those under PHS Act section 2799A–10, ERISA section 725, and Code section 9825?

Answer: There should *NOT be* different definitions of prescription drug for the different types of plans. Each plan shares one common reference nomenclature for prescription drugs – the NDC. For that reason, consistent with our response to question 3, we urge the Departments and OPM to adopt the NDC-11 as the definition of a prescription drug for plan reporting purposes.

Question 5: What considerations should the Departments and OPM take into account in defining the term ''therapeutic class''? How do plans and issuers currently classify prescription drugs by therapeutic class? Does the classification method rely on proprietary software, and how would the choice of therapeutic classification method influence plan and issuer operational costs?

Answer: The Departments and OPM should not define or collect data based on therapeutic class. Section 204 does not require that therapeutic class be defined or that data be collected based on therapeutic class. There are multiple therapeutic class protocols available today (e.g., USP-DC and USP-MMG), and no two protocols agree on either class definition or assignment parameters. Information concerning drug use and classification by therapeutic class is specific to each drug. In addition, an individual drug may qualify to be included in more than one therapeutic class because it may be prescribed to treat different illnesses or conditions. Given that different plans use different therapeutic class definitions, and the same drug may be included in multiple therapeutic classes, any definition the Departments and OPM adopt will yield confusing results that will not meet the objectives and requirements of § 204. We urge the Departments and OPM to collect and report data based on NCD-11, which will provide consistent data useful to stakeholders and the general public.

Question 9: Should the Departments and OPM collect information on rebates, fees, and any other remuneration at the total level or broken out by relevant subcategories? For example, in the PBM Transparency for Qualified Health Plans (QHPs) data collection, PBMs will report information for retained rebates, rebates expected but not yet received, PBM incentive payments, price concessions for administrative services from manufacturers, all other price concessions from manufacturers,

amounts received and paid to pharmacies, and spread amounts for retail and mail order pharmacies. Should the Departments and OPM use the same or similar subcategories for the reporting requirements under PHS Act section 2799A–10, ERISA section 725, and Code section 9825?

Answer: We strongly recommend the Departments and OPM collect information on rebates, fees, and other direct and indirect renumeration (DIR) that are exchanged between Plans and their PBMs and manufacturers and also collect information on fees and other DIR exchanged between pharmacies and Plans and their PBMs. As has been documented in the Medicare program, these payments between Plans/PBMs and manufacturers impact patients' out-of-pocket costs, and can directly affect how patients are covered, and in what amounts. We believe this information would be highly relevant to any subsequent reports issued by the Departments and OPM, and they should be fully captured at the NDC-11 level for each drug on a Plan formulary.

In addition to traditional discounts and rebates, we recommend that the Departments and OPM ask Plans and their PBMs to report on "DIR fees" and other fees that Plans and their PBMs charge pharmacies, including but not limited to switch fees, processing fees, quality program fees and holdbacks, and all other fees withheld by Plans/PBMs from pharmacies until the pharmacy "earns back" the payment. Each of these is a hidden cost to consumers and pharmacies, often doing little more than unnecessarily inflating Plan and PBM profits by extracting "pay-to-play" payments from pharmacies. It is important that the Departments and OPM understand this dynamic and seek to gain a clear understanding of how funds flow to and are retained by the Plans, and is equally important to stakeholders and the general public.

Question 10: Are there types of payments that flow from plans, issuers, or PBMs directly to drug manufacturers? If so, how should these payments be treated? Should they be netted against rebates and other price concessions that are received from drug manufacturers?

Answer: Such payments exist and should be collected and separately reported. There are myriad fees that flow from plans and issuers and their PBMs to drug manufacturers, including service fees, data fees, and various miscellaneous fees. Since these fees generally are not netted against rebates or other price concessions, it is essential that the Departments and OPM require that these fees be reported, separately analyzed, and publicly disclosed.

Question 11: Are there types of rebates and price concessions that are passed directly to the participant, beneficiary, or enrollee? If so, how should they be treated? Should they be included or acknowledged in this data collection?

Answer: There may be rebates and price concessions passed directly to the participant, beneficiary, and enrollee, and the Departments and OPM should collect and publicly disclose this information in as much detail as possible. This is a complex issue that has been addressed in the context of the Medicare Prescription Drug (Part D) program and its "Rebate Rule."[3] Consistent with our recommendations above, and so that the Departments, OPM, stakeholders and the general public have full transparency, we recommend that the Departments and OPM collect and report this information.

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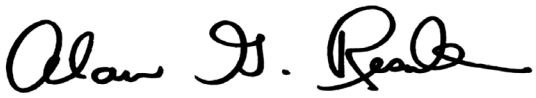
SCPC thanks the Departments and OPM for the opportunity to comment on the RFI. We strongly support efforts to increase transparency across the complex drug pricing arena, and urge the Departments and OPM to focus on the specific LTC pharmacy sector along with your other inquiries. Thank you for your consideration of these comments. We welcome any questions you may have. Please feel free to contact me at (717) 503-0516 or arosenbloom@seniorcarepharmacies.org.

Respectfully submitted,



Alan G. Rosenbloom
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[3] The original Final Rule can be found at 85 Fed. Reg. 76666 (November 30, 2020). The Rule was immediately challenged in litigation, Pharmaceutical Care Management Association v. U.S. Department of Health and Human Services, et al., Civil Action No. 21-95 (JDB) (D.D.C.), and is currently stayed subject to an injunction entered by the Court. Simultaneously, the Administration has deferred implementation of the rule until at earliest December 15, 2021.