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January 16, 2018

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4182-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-4182-P Medicare Program: Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program

To Whom It May Concern:

The American Society of Consultant Pharmacists (ASCP), is pleased to have the opportunity to comment on select provisions of the Center for Medicare and Medicaid Services Proposed Policy Changes and Updates for Medicare Advantage and the Prescription Drug Benefit Program for Contact Year 2019 (CMS-4182-P). ASCP is the only international professional society devoted to optimal medication management and improved health outcomes for all older persons. ASCP's members manage and improve drug therapy and improve the quality of life of geriatric patients and other individuals residing in a variety of environments, including nursing facilities, sub-acute care assisted living facilities, psychiatric hospitals, hospice programs, home and community-based care. ASCP has a long history of advocating for the medical best interests of people who reside in long-term care facilities and those enrolled in hospice programs. We appreciate CMS' continued concern for the welfare of the frail elderly who rely on the Medicare drug benefit as a vital lifeline.

Our comments are focused on the following sections:

1. Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA)
2. Updating the Part D E-Prescribing Standards
3. Preclusion List and eliminating the requirement for all prescribers writing Medicare Part D prescriptions to enroll or opt out as a Medicare Provider
4. Flexibility in the Medicare Advantage Uniformity Requirements
5. Establishing Limitations for the Part D Special Election Period (SEP) for Dually Eligible Beneficiaries
6. Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types
7. Changes to the Days' Supply Required by the Part D Transition Process
8. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes

9. Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale

1.) <u>Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA)</u>:

Page 56346 & 56347
CMS: Section 1860D–4(c)(5)(C)(ii) of the Act defines an exempted individual as one who receives hospice care, who is a resident of a long-term care facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy, or who the Secretary elects to treat as an exempted individual. Consistent with this, we propose that an exempted beneficiary, with respect to a drug management program, would mean an enrollee who: (1) Has elected to receive hospice care; (2) Is a resident of a long-term care facility, of a facility described in section 1905(d) of the Act, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or (3) Has a cancer diagnosis…

Two commenters suggested exempting beneficiaries in assisted living…

We have not proposed to exempt these additional categories of beneficiaries but we seek specific comment on whether to do so and our rationale.

ASCP Comment: ASCP requests that the exemption be extended to beneficiaries residing in assisted living facilities. Specifically, we request that prescription drug claims submitted by Network Long-Term Care Pharmacies (NLTCPs), as defined in Chapter 5 of the Medicare Prescription Drug Benefit Manual, be exempted from a Part D plan sponsor's pharmacy lock-in, if such lock-in tool is a part of the sponsor's drug management program. NLTCPs are required to meet minimum performance and service criteria. These include performing drug utilization reviews, routinely screening for allergies and drug interactions, identifying potential adverse drug reactions, and identifying inappropriate drug usage. Directing a prescription dispensing to an alternate pharmacy will minimize the benefit of the NLTCPs services.

2.) <u>Updating the Part D E-Prescribing Standards:</u>

Page 56439:
CMS: Proposed adoption of NCPDP SCRIPT version 2017071 as the official Part D E-Prescribing Standard for certain specified transactions, retirement of NCPDP SCRIPT 10.6, proposed conforming changes elsewhere in 423.160, and correction of a historic typographical error in the regulatory text which occurred when NCPDP SCRIPT 10.6 was initially adopted.

ASCP Comment: ASCP applauds the decision to move to the NCPDP SCRIPT Version 2017071. There have been many new messages added to the NCPDP SCRIPT Standard that are needed by the industry which will improve patient safety.

CMS: 423.160(b)), we propose to require use of NCPDP SCRPT 2017071 for the following transactions:

- Prescription drug administration message,
- New prescription requests,
- New prescription response denials,
- Prescription transfer message,
- Prescription fill indicator change,
- Prescription recertification,
- Risk Evaluation and Mitigation Strategy (REMS) initiation request,
- REMS initiation response, REMS request, and
- REMS response.

ASCP Comment: ASCP supports mandating all of the transactions listed.

We also recommend for Prescription Transfer that the individual messages be listed as shown below:

- Prescription Transfer Request
- Prescription Transfer Response
- Prescription Transfer Confirm

For consistency purposes, we suggest that the REMs transactions be shown as:

- Risk Evaluation and Mitigation Strategy (REMS) initiation request
- REMS initiation response
- REMS request
- REMS response

Page 56440

CMS: As such, we are proposing to revise § 423.160(b)(1)(iv) so as to limit its application to transactions before January 1, 2019 and add a new § 423.160(b)(1)(v). The requirement at § 423.160(b)(1)(v) would identify the standards that will be in effect on or after January 1, 2019, for those that conduct e-prescribing for part D covered drugs for part D eligible beneficiaries. If finalized, those individuals and entities would be required to use NCPDP SCRIPT 2017071 to convey prescriptions and prescription-related information for the following transactions:

- Get message transaction.
- Status response transaction.
- Error response transaction.
- New prescription request transaction.
- Prescription change request transaction.
- Prescription change response transaction.
- Refill/Resupply prescription request transaction.
- Refill/Resupply prescription response transaction.

- Verification transaction.
- Password change transaction.
- Cancel prescription request transaction.
- Cancel prescription response transaction.
- Fill status notification.
- Prescription drug administration message.
- New prescription requests.
- New prescription response denials.
- Prescription transfer message.
- Prescription fill indicator change.
- Prescription recertification.
- Risk Evaluation and Mitigation Strategy (REMS) initiation request.
- REMS initiation response, REMS request
- REMS initiation response.
- REMS request.
- REMS response.

ASCP Comment: From the above list, ASCP supports mandating all of the listed transactions except the "Password change transaction" as noted below. Also note that there is no "Resupply prescription response transaction" within the standard.

The following transactions have been renamed in the SCRIPT Version 2017071

- Refill prescription request transaction is now called Renewal prescription request transaction
- Refill prescription response transaction is now called Renewal prescription response transaction

On the above list, New Prescription Request appears twice. The first occurrence of "New prescription request transaction" should be "New prescription transaction". The second occurrence is the correct naming of a new message allowing a pharmacy to request a new prescription be sent for a patient.

- The "Password change transaction" should not be mandated since it is believed to not be used in the industry today.
- As stated in the comments from Page 56439 the "Prescription transfer messages should be named individually. They should appear as:
  - Prescription Transfer Request
  - Prescription Transfer Response
  - Prescription Transfer Confirm
- The following item should be deleted from the list above because it is a duplicate line:
  - REMS initiation response, REMS request

CMS: In addition, we propose to add § 423.160(b)(1)(v) to provide that NCPDP Version 2017071 must be used to conduct the covered transactions on or after January 1, 2019. Furthermore, we are proposing to amend § 423.160(b)(2) by adding § 423.160(b)(2)(iv) to name NCPDP SCRIPT Version 2017071 for the applicable transactions. Finally, we propose to incorporate NCPDP SCRIPT version 2017071 by reference in our regulations. We seek

comment regarding our proposed retirement of NCPDP SCRIPT version 10.6 on December 31, 2018 and adoption of NCPDP SCRIPT Version 2017071 on January 1, 2019 as the official Part D e-prescribing standard for the e-prescribing functions outlined in our proposed § 423.160(b)(1)(v) and (b)(2)(v), and for medication history as outlined in our proposed § 423.160(b)(4), effective January 1, 2019. We are also soliciting comments regarding the impact of these proposed effective dates on industry and other interested stakeholders.

ASCP Comment: ASCP is requesting a transition period be added to the implementation timeline. A transition period has worked well for the industry in the past. We suggest a voluntary use date to be the effective date of the Final Rule and the sunset date for SCRIPT Version 10.6 be 24 months later. Having the transition period would decrease the risk of healthcare delivery delays and interruption. The transition from SCRIPT Version 8.1 to SCRIPT Version 10.6 took approximately three years and provided an opportunity for early adopters to identify any possible issues with documentation or the Standard itself. Additionally, there are many actions that must happen prior to the mandated use of SCRIPT Version 2017071. These time-consuming actions include:

- Design, development, testing by vendors which include prescribing/EHR vendors, pharmacy software vendors, prescribers, pharmacies, payers and intermediaries who route transactions.
  - Release and end user testing
  - Software certification
  - EPCS auditing
  - Training

In addition, ASCP recommends the regulatory compliance date for the NCPDP SCRIPT Standard Version 2017071 not fall on the first of January as it would compound the possible risk of healthcare delivery delays and interruptions. This is due to operational challenges associated with the normal processing and administrative changes occurring with the new Part D plan year beginning on January 1st.

Page 56513
§ 423.160 Standards for electronic prescribing.

CMS: (v) On or after January 1, 2019, the standards specified in paragraphs (b)(2)(iii) and (b)(3), (b)(4)(ii),

ASCP Comment: It is believed the above highlighted reference is incorrect and would allow for the use of the NCPDP SCRIPT Version 10.6 after January 1, 2019. It is believed the reference should be (b)(2)(iv).

CMS: (iv) The National Council for Prescription Programs SCRIPT standard, Implementation Guide Version 2017071 approved July 28, 2017 (incorporated by reference in paragraph (c)(1)(i) of this section), to provide for the communication of a prescription or related prescription-related information between prescribers and dispensers for the following:
(A) Get message transaction.
(B) Status response transaction.

(C) Error response transaction.
(D) New prescription transaction.
(E) Prescription change request transaction.
(F) Prescription change response transaction.
(G) Refill/Resupply prescription request transaction.
(H) Refill/Resupply prescription response transaction.
(I) Verification transaction.
(J) Password change transaction.
(K) Cancel prescription request transaction.
(L) Cancel prescription response transaction.
(M) Fill status notification.
(N) Prescription drug administration message.
(O) New prescription requests.
(P) New prescription response denials.
(Q) Prescription transfer message.
(R) Prescription fill indicator change.
(S) Prescription recertification.
(T) REMS initiation request.
(U) REMS initiation response.
(V) REMS request.
(W) REMS response.

ASCP Comments: It is believed the above highlighted reference is incorrect and should reference (c)(1)(vii).

For the transactions listed above:

- ASCP supports mandating all of the listed transactions with the exception of "Password change transaction" as noted below. Also note that there is no "Resupply prescription response transaction" within the standard.

- The following transaction have been renamed in the SCRIPT Version 2017071
  - Refill prescription request transaction is now call Renewal prescription request transaction
  - Refill prescription response transaction is now called Renewal prescription response transaction
- ASCP is requesting the "Password change transaction" not be mandated since it is believed to not be used in the industry today.
- As stated in the comments from Page 56439 ASCP is requesting the "Prescription transfer messages be named individually. They should appear as:
  - Prescription Transfer Request
  - Prescription Transfer Response
  - Prescription Transfer Confirm

General Comments on NCPDP Script Version 2017071:
The use of the NCPDP SCRIPT Version 2017071 needs to be reconciled with other government programs requiring the use of SCRIPT Version 10.6 such as the CMS Electronic

Health Record Incentive Program Stage 3 and the ONC 2015 Edition Health IT Certification Criteria.

The industry understands there may be concern that the Prior Authorization transaction name under HIPAA would suffice for the e-Prescribing workflow. It is clear upon studies and research by the industry that the Prior Authorization transaction named under HIPAA is for medical benefits and is not conducive to exchange of information related to prior authorizations about the drug benefit. The industry feels the NCPDP SCRIPT ePA transactions are important to mention with the comments for this NPRM. The process for the creation of the NCPDP SCRIPT ePA transactions started in 2006 with an e-Prescribing pilot specific to the X12 278, 275 and PA attachments transactions which were found to be sub-optimal for the support of prior authorizations for medications.

The National Committee on Vital and Health Statistics (NCVHS) in a letter from May of 2014, stated the following:
"In 2004, the National Council for Prescription Drug Programs (NCPDP) organized a multi-industry, multi-Standards Development Organization task group to evaluate a prior authorization (PA) standard, particularly the medication prior authorization, that would support the needs for e-prescribing transactions and to develop a solution. Investigators found that the HIPAA-named PA standard (the X12N 278 v4010 or v5010), was not adequate to support medication PA because it was designed for procedures/services or durable medical equipment (DME) prior authorization and did not accommodate the information necessary to facilitate prior authorization. It also did not have a mechanism for providers to provide relevant information for e-prescribing. Consequently, the NCPDP developed and through its vetting process, received industry approval for e-Prescribing Prior Authorization transactions (included in the NCPDP SCRIPT Standard), which enables the healthcare industry to exchange prescriber-initiated prior-authorization requests for prescribed medications as part of the provider-patient encounter."

In the same letter, NCVHS recommended to the Secretary of Health and Human Services that the prior authorization transactions found in NCPDP SCRIPT Version 2013101 be adopted for the exchange of prior authorization information between prescribers and processors for pharmacy benefits. They also recommend the standard be named in the most appropriate regulation and at the earliest possible time.

Currently, the NCPDP SCRIPT ePA transactions have been adopted by more than 60% of the pharmacy benefit managers. In addition, many proprietary solutions have and are being created for ePA. The use of these transactions cut the approval time of prior authorizations to hours instead of days leading to the speedier therapy for the patient which results in improved outcomes.

Benefits of adopting the NCPDP SCRIPT Version 2017071 ePA transactions are

- ePA supports the proposed measures for the 2021 Star Ratings in which the plans will be scored on how easy it is for members to get the prescriptions they need (page 215). ePA expedites this process in that most determinations happen within minutes/hours vs. days.

- The inclusion of the NCPDP SCRIPT Standard ePA transactions helps CMS achieve the intent of supporting innovative approaches to improving program quality, accessibility and improvement in the CMS customer experience.
- Utilization of these transactions also reduces the burden for all participants in the CMS Medicare Part D program.
- ePA transactions would also support CMS's intent of establishing a framework and addressing the opioid epidemic, under Part D, in which plan sponsors may establish a drug management program for beneficiaries at risk for prescription drug abuse or misuse. The ePA process is the clinical backbone as it can help answer clinical and utilization questions before an opioid is prescribed or dispensed. Handling the authorization process via paper makes little sense as it slows the process and inhibits good information sharing on potential abuse, paper is not within the prescriber's workflow and therefore leads to a gap in interoperability. This will save significant time and resources and allow doctors to spot problems and halt scripts for patients who may be abusing opioids.
- CMS has identified an intent to reduce the burden related to printing and mailing, reduce the number of paper documents that plans have to provide. By adopting the ePA process, additional paper burden could be reduced for the plan(s) and the prescribers in that the PA determination process would be electronic and would eliminate the need for the plan to send the prescriber a paper version of the determination.
- MA and Part D Ratings System – ePA aligns with enhancement efforts to utilize measures developed by consensus-based organizations. NCPDP is one of the most recognized consensus-based organizations and the SCRIPT ePA Transactions are such measures. – See page 174.
- ePA utilization via the NCPDP SCRIPT Standard creates expeditious access for CMS customers (patients) to their needed medications, speeds their time to therapy for those needed medications which improves patient outcomes, reduces medical spend due to decreased emergency care and brings quality to the system. As outlined in the Part D Star Performance Measures in Table 2B – When plans utilize ePA vs paper PA methods they are more likely to see a higher percent score on the Measure – Getting Needed Prescription Drugs. ePA also is proven to improve speed to therapy for the medication adherence for the specific disease states outlined in Table 2B (see page 216) Diabetes, Hypertension and Cholesterol, improving the plans outcomes for these measures.
- Unbalanced process right now at the state level, having something at a federal level could help stabilize adoption in the states.

ASCP respectfully requests the NCPDP SCRIPT Version 2017071 Prior Authorization transactions be named in a regulation as it is currently part of the pharmacy industry prior authorization process.

3) Preclusion List and eliminating the requirement for all prescribers writing Medicare Part D prescriptions to enroll or opt out as a Medicare Provider.

Page 56444

CMS: We are proposing to delete the current regulations that require prescribers to enroll in or opt out of Medicare for a pharmacy claim (or beneficiary request for reimbursement) for a Part D drug prescribed by a physician or eligible professional to be covered. …. Instead, we would require plan sponsors to reject claims for Part D drugs prescribed by prescribers on the preclusion list. We believe this latter approach would better facilitate our dual goals of reducing prescriber burden and protecting the Medicare program and its beneficiaries from prescribers who could present risks.

ASCP Comment: ASCP applauds removing the requirement to enroll or opt out of Medicare for prescribers writing prescriptions covered under the Medicare Part D program. We believe the new preclusion list is a viable alternative to the enrollment. However, ASCP asks that CMS have specific administrative procedures in place to ensure that prescriptions dispensed without the pharmacy knowing a prescriber is on the preclusion list are adjudicated appropriately.

- Will there be an electronic database file available to check the preclusion list on a regular basis?
- Can this list be integrated in pharmacy software systems to ensure that medications are not dispensed if the prescriber is on the list?
- While we understand that the 90 day rule would be followed for these prescriptions, many times the pharmacy needs to send out medications for a nursing home beneficiary, and unless the list if readily available electronically, who will be responsible for payment of these medications?

4) Flexibility in the Medicare Advantage Uniformity Requirements:

CMS proposes to modify the Medicare Advantage Uniformity requirements to provide common-sense accommodations for plans to provide disease-specific services to enrollees. ASCP supports this proposal. By creating allowances for plans to provide services that help enrollees better manage medical conditions CMS will move closer to achieving the important goal of providing higher quality care at a more affordable cost, both for the enrollee and for the program.

Consultant pharmacists are well positioned to provide specialized services for enrollees with diabetes, heart failure, dementia and a host of other diseases with high prevalence among the Medicare population. We believe CMS' proposal will make it easier for Medicare Advantage plans to create effective programs and target them to beneficiaries with a demonstrated need.

5) **Establishing Limitations for the Part D Special Election Period (SEP) for Dually Eligible Beneficiaries**:

CMS notes that very few dual eligibles take advantage of the opportunity to exercise their right to unlimited SEPs. However, CMS is concerned that some duals could be disadvantaged if they exercise their right to a SEP during the plan year.

Page 56473
CMS: In section II.A.11. of this rule, we propose to revise § 423.38(c)(4) to limit the SEP for dual- and LIS-eligible individuals. The provision would make the SEP for FBDE or other subsidy-eligible individuals available only in the following circumstances:
• For beneficiaries who are making an allowable onetime-per-calendar-year election.
• For beneficiaries who have been assigned to a plan by CMS or a state (that is, through auto enrollment, facilitated enrollment, passive enrollment, or reassignment) and decide to change plans following notification of the change or within 2 months of the election effective date.
• For beneficiaries who have a change in their dual or LIS-eligible status.

ASCP Comments: ASCP recognizes that the SEP is not widely-used by the overall LIS population, however it provides an important avenue to access for those LIS beneficiaries who do elect to use the SEP. ASCP is concerned that this policy becomes even more dangerous when combined with the proposed policy revisions to midyear formulary changes. Some LIS beneficiaries may be unable to maintain a treatment regimen to a branded drug when a generic equivalent enters the market as the branded drug may be removed from the formulary.

Under current policy, in this scenario, the LIS beneficiary may switch to a plan still covering the product. This is an important and strong protection for low-income beneficiaries and we strongly suggest CMS consider expanding the limit to 2 to 3 SEPs during a plan year. This is an example of CMS fixing a problem that, through its own admission, does not exist but could cause access issues for some beneficiaries
ASCP further requests confirmation that dual- and LIS-eligible individuals moving into, or moving out of, a LTC facility will continue to be entitled to a "SEP for Institutional Individuals" as defined in Chapter 3 Medicare Prescription Drug Benefit Manual.

6) **Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types**:

CMS expresses concern that the evolution of preferred pharmacy networks has resulted in circumventing the any willing provider requirement of the statute.

Page 56408
CMS: Therefore, we are clarifying in this preamble that although Part D sponsors may continue to tailor their standard terms and conditions to various types of pharmacies, Part D

plan sponsors may not exclude pharmacies with unique or innovative business or care delivery models from participating in their contracted pharmacy network on the basis of not fitting in the correct pharmacy type classification. In particular, we consider ''similarly situated'' pharmacies to include any pharmacy that has the capability of complying with standard terms and conditions for a pharmacy type, even if the pharmacy does not operate exclusively as that type of pharmacy.

ASCP Comments: ASCP is supportive of this clarification. Additionally, we would like to restate our continuing support for the Performance and Service Criteria for Network Long-Term Care Pharmacies as defined in Chapter 5 (50.5.2) of the Medicare Prescription Drug Benefit Manual. We believe that the ten criteria listed in the manual fairly define the minimum performance and service criteria for any pharmacy wishing to contract with a Part D sponsor as a Network Long-Term Care Pharmacy.

7) **Changes to the Days' Supply Required by the Part D Transition Process**
CMS proposes to reduce the current requirement for a 91-98-day supply of non-formulary drugs for patients transitioning from another health plan to a "month's supply". CMS explains that experience shows that the need for the longer time frame does not appear to be necessary. The agency is also concerned about the potential waste involved with 91-day supplies.

Page 56411 & 56412
CMS: First, we propose to shorten the required transition days' supply in the long-term care (LTC)
setting to the same supply currently required in the outpatient setting…

However, we now believe that CMS could eliminate additional drug waste and cost by no longer requiring a longer transition days' supply in the LTC setting.

ASCP Comments: CMS has had a longstanding policy of allowing LTC residents a 3-month supply of non-formulary medications during periods of transition. CMS correctly recites the history of this policy but suggests that the need for longer transition for LTC residents did not appear to materialize during the period since the policy was first approved. CMS is also concerned that the longer transition policy may result in more drug waste.

Given the higher levels of acuity among residents in LTC facilities, as well as medication regimens that often include 10-12 different drugs, we have reservations about this proposed policy and urge CMS to reconsider. With new incentives to move residents to home and community-based care alternatives, this trend of treating high acuity patients is likely to continue. It is clinically unsound to expose frail, medically-sensitive residents to a tighter timeframe in which it might be necessary to adjust several medications, especially as many drug trials should extend at least 4-6 weeks to assess for efficacy. Optimally, no more than one medication should not be changed simultaneously. Residents stabilized on a complex medication regimen presents unique challenges when making therapeutic interchanges. Changing two or more drugs simultaneously within a 30-day period would not allow you to

ascertain which drug caused a problem if therapy resulted in adverse reactions. We believe maintaining the three-month requirement will result in fewer therapeutic mishaps.

Additionally, for those LTC pharmacies utilizing post-consumption (or retrospective) billing at the end of a month, a 30-day transition period could be nearly exhausted by the time a bill is generated and the need for transition is identified.

CMS' concern over additional drug waste is not warranted. Even though the current policy allows to up to three months transitional coverage, the policy does not anticipate the total supply to be dispensed at one time. Rather, the policy anticipates an initial one-month supply followed by an additional two refills of one month each.

ASCP encourages CMS to maintain the current policy on length of transition for residents of LTC facilities.

8) Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes:

Current policy requires plans to submit a formulary change request when proposing to eliminate a brand name drug in favor of a generic. It also requires the plan to provide 60-day notice to plan enrollees prior to implementing the formulary change. CMS proposes to allow plans to implement formulary changes involving eliminating branded drugs in favor of generic equivalents without prior approval from CMS. The plans would be allowed to make these changes any time during the calendar year.

ASCP Comments: We agree with CMS' proposal to allow plans to implement formulary changes involving eliminating branded drugs in favor of generic equivalents without prior approval from CMS in order to help reduce costs.

We don't believe that eliminating notice of the changes are in the best interest of patient care. The current notification affords the beneficiary time to explore how a transition to a generic drug will affect their treatment regimen. A change in copayment and a change in pill size, shape, or color could cause undue stress on beneficiaries. Ample notification is best for patients.

Secondly, the supply chain must have time to adapt to these changes, especially when a new generic drug comes on the market. This is especially important for patients in LTC facilities. Without adequate notification, the LTC pharmacy may not have the generic medication in stock. If this is a new generic drug, the wholesaler that the pharmacy purchases from may not have it in stock which would further delay obtaining the medication. If the LTC pharmacy receives a new or refill order for a patient, they may learn at submission that the brand is no longer covered. If the generic is not currently stocked by the pharmacy, it could result in a delay of treatment. Because of this, we recommend that plans be required to notify network long-term care pharmacies of generic substitution changes in advance of implementing the change in formulary to allow adequate time to procure the medication.

9) Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale:

CMS notes that PDPs have been very successful in extracting rebates from manufacturers and in negotiating price concessions from pharmacies. These price concessions have not resulted in lower cost sharing to beneficiaries, but may have resulted in lower plan bids based on cost of acquisition and dispensing.

CMS is asking for comment on how this system could be improved to provide greater transparency and lower cost sharing for beneficiaries. Information received will guide further rulemaking in the future.

Page 56426

CMS: We are considering revising the definition of negotiated price at § 423.100 to remove the *reasonably determined* exception and to require that all price concessions from pharmacies be reflected in the negotiated price that is made available at the point of sale and reported to CMS on a PDE record, even when such concessions are contingent upon performance by the pharmacy.

ASCP Comments: ASCP strongly supports the revised definition of negotiate price and the requirement that all price concessions from pharmacies (pharmacy DIR fees) are to be reflected in the negotiated price that is made available at the time a medication is dispensed. This approach would provide greater transparency, enhance the predictability of business operations, and, as CMS concluded, lead to significant beneficiary savings.

Currently, DIR fees are assessed retroactively, often weeks or even months after a prescription has been filled. This creates uncertainty for the pharmacy as to what its net reimbursement for dispensing a medication will be. Such a delay imposes an unnecessary burden on pharmacy operators as they assess their ability to invest in and grow their pharmacies. Furthermore, the sheer magnitude of these fees, which can often amount in the tens of thousands of dollars annually, often forces pharmacies to make tough decisions to reduce employee hours, or in some cases, lay off employees. Such actions have a negative, ripple effect on beneficiary access and care.

Further, if CMS requires all pharmacy price concessions to be accounted for at point-of-sale, PBMs and PDPs would still maintain the ability to create quality-based incentives that reward pharmacies for achieving contractual, performance-based metrics based on the medication dispensed and patients and disease states being managed appreciating the nuances that exist across pharmacy practice settings. These quality-based payments can be accounted for and reported to CMS as a negative DIR.

In addition to the benefits to pharmacies, CMS has indicated that, even when considering the potential for slight increases in monthly premiums that CMS predicts, beneficiaries would realize net savings of $10.8 billion. This would also slow beneficiary progression through the

phases of the Part D program. These conclusions align with CMS' previous findings that DIR affects beneficiary cost-sharing and CMS payments to plans while also pushing patients into, and through, the coverage gap sooner.

Finally, CMS recognized that several research studies demonstrate that the higher patient cost-sharing that results from retroactively applying pharmacy DIR fees can impede beneficiary access to necessary medications. As former Surgeon General C. Everett Koop noted, medications don't work in those who don't take them. Thus, the result is often poorer health outcomes and higher costs to the health care system as patients seek costlier treatments. Requiring pharmacy DIR fees to be reported at point-of-sale could create greater savings to Medicare by promoting medication access and adherence.

Given the overall patient savings predicted by CMS and the enhanced transparency created by these provisions, we believe that CMS acted prudently by considering them in this proposed rule. We urge CMS to act swiftly in adopting a requirement to account for all pharmacy DIR at point-of-sale.

Additionally, ASCP continues to maintain its position that DIR fees are inappropriate for prescriptions for beneficiaries residing in long-term care. The long-term care pharmacy, along with the long-term care facility, the consultant pharmacist, and prescriber, provide an enhanced level of medication related clinical services. Further plan or PBM medication related clinical services will not provide any additional benefit in this setting and therefore are not required.

Conclusion

Thank you for the opportunity to address comments on this important document and please accept our offer of any assistance we might provide in order to continue to improve the Medicare Drug Benefit.

Sincerely,

Frank Grosso
Executive Director & CEO