January 16, 2018

VIA Electronic Submission at: http://www.regulations.gov

Administrator Seema Verma
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-4182-P
P.O. Box 8013
Baltimore, MD 21244-80131

RE: Proposed Rule for 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 (CMS-4182-P)

Dear Administrator Verma:

On behalf of McKesson Specialty Health, please accept for your consideration the following comments regarding the Centers for Medicare and Medicaid Services' ("CMS") Proposed Rule for 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 (collectively, the "Proposed Rule").

Over the past decade, the availability and use of oral oncolytics as an effective cancer treatment option has significantly increased. In comparison to traditional intravenous (IV) chemotherapy treatment, oral oncolytics present an easier, more convenient route of administration for patients. Oral oncolytics have been shown to be safer and more effective than traditional IV chemotherapy treatments. However, despite the increased effectiveness of oral oncolytics, patient access and adherence has remained a key barrier to positive patient outcomes.

To improve patient access and adherence, many community-based cancer clinics, including many practices supported by McKesson Specialty Health, have established integrated in-office dispensing ("IOD") platforms or practice-based pharmacies. Under these models, patient care is more responsive and tailored to the state of the patient's health allowing for improved education, reduced time-to-treatment and enhanced coordination of the care plan. Patients are able to conveniently access their oral chemotherapy prescriptions or other medications at the point-of-care. Importantly, practices whose care plans have medically integrated pharmacy services have been shown to significantly improve patient adherence,[1] ensure the timely receipt of prescribed drugs, [2] and improve outcomes [3] at a lower cost. [4]

[1] Pauline W. Chen, *When Patients Don't Fill Their Prescriptions*, N.Y. Times (May 20, 2010), available at: http://www.nytimes.com/2010/05/20/health/20chen.html?_r=0.
[2] Lee Schwartzberg et al., *Abandoning Oral Oncolytic Prescriptions at the Pharmacy: Patient and Health Plan Factors Influencing Adherence* (2010), available at: http://www.communityoncology.org/pdfs/asco-poster-handout.pdf.
[3] Michael A. Fischer et al., Primary Medication Non-Adherence: Analysis of 195,930 Electronic Prescriptions, 25 J. Gen. Intern. Med. 284 (Apr. 2010), available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2842539/pdf/11606_2010_Article_1253.pdf.
[4] See William Shell, The History of Physician Dispensing, Complete Claims Processing Inc., available at: http://www.ccpicentral.com/history-of-physician-dispensing.php (last visited Jan. 10, 2018).

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Practices engaged in the dispensing of oral oncolytics and other specialty drugs through IOD platforms or practice-based pharmacies have participated in Medicare Part D pharmacy networks since the implementation of the program. These innovative practice models, shown to improve outcomes and reduce costs, will be directly impacted by changes to the Part D program. Here, the Proposed Rule's request for information ("RFI") regarding Pharmacy Price Concessions to Drug Prices at the Point of Sale and provisions addressing Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types will have significant bearing on the continued success of medically integrated pharmacy services in this the country. Thus, it is important that CMS consider the impact that the Proposed Rule will have on the ability of cancer patients to receive innovative, high-quality and integrated care at a low cost.

On behalf of the nation's leading community cancer care providers, we appreciate the opportunity to provide comments on the Proposed Rule and thank you for your consideration.

I. Request for Information Regarding the Application of Pharmacy Price Concessions to Drug Prices at the Point of Sale

McKesson Specialty Health agrees with CMS's position that the current structure for pharmacy price concessions fails to allow for meaningful price comparisons, does not encourage price transparency, and is not optimal for producing the lowest overall prescription drug costs for beneficiaries -- ultimately costing taxpayers. Furthermore, the current use of retroactive pharmacy price concessions serves as a disincentive to practices wishing to establish or expand IOD platforms and practice-based pharmacy operations, thereby impeding the growth of integrated care models that have been proven to improve patient outcomes.

McKesson Specialty Health is generally supportive of CMS's proposed revision of the definition of negotiated price at § 423.100 to remove the reasonably determined exception and require all price concessions from pharmacies be reflected in the negotiated price at the point of sale. The current use of the exception by plan sponsors and pharmacy benefit managers ("PBMs") has been applied in an overly broad and unintended fashion that has resulted in higher profit margins for plan sponsors and PBMs with little to no reciprocal benefit to patients. McKesson Specialty Health is supportive of alternative models that will represent a larger share of pharmacy price concessions in the negotiated price. This includes CMS's "Lowest Possible Reimbursement" proposal.

Alternative models that apply pharmacy price concessions at the point of sale, such as the proposed Lowest Possible Reimbursement model proposed by CMS, will have a positive effect on Part D program beneficiaries. Including pharmacy price concessions at the point of sale will result in lower out-of-pocket costs to beneficiaries. CMS's own calculations show that having all pharmacy price concessions reflected as part of the negotiated price will reduce net beneficiary costs by approximately $10.4 billion.

The Lowest Possible Reimbursement model and similar approaches that avoid retroactive pharmacy price concessions will also remove one of the major disincentives for establishing or expanding medically integrated pharmacy services and practice-based pharmacy operations, economic uncertainty. As CMS notes, pharmacy price concessions are calculated and applied retrospectively, often many months after claims have been submitted and reimbursed. Practices, already operating on thin margins, are left to simply speculate the amount of PBM "clawbacks" months after the point of sale. Unfortunately, practices have limited ability to positively impact the level of DIR fees assessed as they are frequently based on targets outside of the practice's control such as CMS star ratings. The DIR fees can also be percentage based magnifying the negative impact on practices dispensing high-priced specialty medications via IOD solely due to the types of patients and subsequent costs associated with their treatments. McKesson Specialty Health urges CMS to eliminate retroactive pharmacy price concessions to increase transparency, lower patient out-of-pocket costs and provide greater predictability to pharmacies.

II. Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types

A crucial component of the beneficial oral oncolytic model outlined above is the ability for IOD practices and physician-owned pharmacies to be afforded treatment as in-network providers to Medicare Part D plans. The longstanding role of physician practices with medically integrated pharmacy services in the delivery of care under Medicare Part D is exemplified by the fact that dispensing physicians have participated as in-network providers ever since the implementation of the Medicare Part D program in 2006. In addition to the quantifiable improved health outcomes and overall cost of care savings outlined above, the inclusion of IOD in Medicare Part D networks offers patients more choices in how they would like to source their care. This is especially critical in a marketplace where providers and payers face constant consolidation pressure to the detriment of both care and competition.

In 2016, CMS itself further recognized the immense impact and importance of IOD in patient care by weaving into its new Oncology Care Model ("OCM") a focus on physician-led care. Notably, CMS's OCM model explicitly contemplates not only physician-administered drugs billed under Medicare Part B but also outpatient prescription drugs dispensed by physicians and billed under Medicare Part D. [5] This was in deference to the immense clinical value of integrating physician-led care with seamless access to traditional oncolytics delivered pursuant to Medicare Part B and oral oncolytics delivered under Part D.

While McKesson Specialty Health applauds CMS continuing inclusion of provider-based pharmacies under the umbrella of non-retail pharmacies and CMS's position that the any willing pharmacy requirement applies to all pharmacies, regardless of how a pharmacy has organized one or more lines of pharmacy business, McKesson Specialty Health strongly encourages CMS to consider regulatory language or additional commentary which also strengthens IOD physicians' longstanding inclusion as in-network Part D providers.

This request is due to that fact that, in 2016, a single PBM with significant market share sought to unilaterally interpret Medicare Part D to only provide for pharmacy-only networks and that IOD and physician-owned pharmacies were therefore necessarily "out-of-network." The PBM also went so far as to issue notices to IOD physicians of the same, alerting that the physician dispensing class of trade would no longer be included in the PBM's Part D network.

Ultimately, the PBM reversed its position amid a wave of backlash from patients, patient support groups, professional organizations, and a diverse spectrum of industry stakeholders. Nevertheless, the importance of IOD to patient care, patient choice, and the overall marketplace necessitates careful consideration of CMS's application of the any willing pharmacy requirement. An interpretation or definition that too narrowly tailors the concept of pharmacy may create confusion and prompt PBMs to wholesale exclude IOD physicians from Medicare Part D networks. McKesson Specialty Health strongly believes that any broad-based exclusion of IOD physicians from Medicare Part D in-network provider status would have potentially disastrous effects on the quality of patient care and costs.

McKesson Specialty Health respectfully requests that CMS consider regulatory language or additional commentary to strengthen IOD physicians' inclusion as in-network Part D providers. In particular, McKesson Specialty Health encourages CMS to consider regulatory language or commentary that establishes that duly licensed providers authorized by the health practice laws of their state to dispense outpatient drugs to the patients are afforded the same treatment as a pharmacy for the purposes of Part D's any willing pharmacy requirement. Taking this position would be (1) consistent with continuing IOD physicians' longstanding and continuous participation in Medicare Part D as in-network providers; (2) help avoid confusion which may lead to the unwarranted ejection or

[5] See U.S. Dept. of Health & Human Svcs., HHS Announces Physician Groups Selected for an Initiative Promoting Better Cancer Care (Jun. 29, 2016), originally available at: http://www.hhs.gov/about/news/2016/06/29/hhs-announces-physician-groups-selected-initiative-promoting-better-cancercare.html now achieved by DHHS request at http://wayback.archive-it.org/3926/20170129023002/https://www.hhs.gov/about/news/2016/06/29/hhs-announces-physician-groups-selected-initiative-promoting-better-cancer-care.html; see also CMS, Oncology Care Model; https://innovation.cms.gov/Files/x/ocm-druglist.xlsx (listing covered medication and those payable under Part B or Part D respectively).

exclusion of IOD physicians from Medicare Part D networks; and (3) align Medicare Part D's network provider participation standards with CMS's broader OCM initiative which expressly contemplates physicians and physician practice groups participating in the administration of traditional oncolytics under Medicare Part B and oral oncolytics under Medicare Part D.

We thank you for the opportunity to provide comments on these important issues and respectfully ask that CMS consider the impact that the Proposed Rule will have on the oncology community and the countless patients that benefit from IOD and in-house pharmacy operations.

Sincerely,

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