January 15, 2018

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Seema Verma, M.P.H. Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

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

Dear Administrator Verma:

BioScrip, Inc. thanks you for the opportunity to comment on the proposed 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 (CMS-4182-P; RIN 0938-AT08), 82 Fed. Reg. 56336 (November 28, 2017) ("the Proposed Rule"), and particularly on the Prescription Drug Benefit (or Part D) proposals in the rulemaking. We appreciate the opportunity to share our comments with the Agency in the hopes of improving and refining the proposed rule changes.

About BioScrip: BioScrip is the largest independent national provider of infusion and home care management solutions, with approximately 2,200 teammates and nearly 80 service locations across the U.S. BioScrip works with physicians, hospital systems, payors, pharmaceutical manufacturers and skilled nursing facilities to provide patients access to post-acute care services. We operate with a commitment to bring customer-focused pharmacy and related healthcare infusion therapy services into the home or alternate-site setting. By collaborating with the full spectrum of healthcare professionals and the patient, BioScrip provides cost-effective care that is driven by clinical excellence, customer service, and values that promote positive outcomes and an enhanced quality of life for those it serves.

Our nationwide service capabilities and ability to deliver clinical management services allows patients, including Medicare beneficiaries, to receive high-touch treatment in a community-based or home-based care environment. Through our skilled multidisciplinary team of clinicians, including pharmacists, nurses, dieticians and respiratory therapists, we work with physicians to develop a plan of care suited to each patient's specific needs. Whether in the home, physician office, ambulatory infusion center, skilled nursing facility or other alternate sites of care, we provide products, services and condition-specific clinical management programs tailored to improve the care of individuals with complex health conditions such as gastrointestinal abnormalities, infectious diseases, cancer, multiple sclerosis, organ and blood cell transplants, bleeding disorders, immune deficiencies and heart failure. Because many of our patients are

Medicare beneficiaries, and many of the medications we infuse are subject to reimbursement under the Medicare Prescription Drug benefit, we have a great interest in the recent proposed rule and offer our comments on several of the proposals below.

I. Proposed Any Willing Pharmacy Clarification

The Proposed Rule: BioScrip appreciates CMS's proposed revisions to the "any willing pharmacy" (AWP) regulations, and the Agency's recognition that Part D sponsors have "circumvent[ed] the any willing pharmacy requirements and inappropriately exclude[ed] pharmacies from network participation" through "preferred" rather than "standard" agreements. 82 Fed. Reg. at 56407. AWP is an essential requirement of the Part D program to secure beneficiary access in general and to ensure that beneficiaries receiving home infusion drugs have access to pharmacies that have the skills and ability to provide needed medications. We particularly appreciate the Agency's clear direction that "a Part D plan sponsor must not preclude a pharmacy from network participation as a retail pharmacy because that pharmacy also operates a home infusion book of business, or vice versa," *id.*, and urge the Agency to reiterate that example in the final rule and in regulatory text itself. We also applaud the Agency's proposed adoption of a definition of "mail order pharmacy" and its clarification that home infusion pharmacies are not mail order (even if they occasionally may use the mail for shipment of certain drugs). 82 Fed. Reg. at 56409.

Part D Plans have a specific home infusion pharmacy network adequacy standard in regulation, 42 C.F.R. 423.120(a)(4), and that standard has been clarified by several CMS program memoranda.[1] However, over the years Part D Sponsors have routinely tried to keep home infusion pharmacies out of network by severely limiting access to AWP contracts or requiring such restrictive and unfair terms that the available AWP agreements are commercially impractical. To ensure that the AWP proposed regulations have meaning, we urge the Agency to reiterate in clear terms that "Retail" and "Mail Order" pharmacies, as defined by the proposed regulation which we support, should not be included in the calculation of home infusion network adequacy. Stated differently, CMS has recognized in the proposed rule that "many pharmacies no longer fit squarely into traditional pharmacy type classifications," 82 Fed. Reg. at 56408, and that while the "definitions were never intended to limit the scope of the [AWP] requirement" they are in fact doing so. *Id.* CMS should make clear in its Final Rule that home infusion is not retail or mail order, and vice versa.

With those qualifications, BioScrip supports the Agency's proposal to require that Part D sponsors make AWP contracts available no later than September 15 of each year to allow sufficient time for the pharmacy to review the contract. Similarly, we support CMS's proposed new definition of 'retail," particularly incorporating the concept of the pharmacy being open to the "walk-in general public" as a crucial element of the definition. 82 Fed. Reg. at 56409.

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[1] *See, e.g.,* Memorandum dated January 26, 2010, available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Adequate-Access-to-HI-Pharmacies-Rewrite-012610.pdf and Memorandum dated December 22, 2010, available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/HPMSMEMORetailHIAccess.pdf . See also Medicare Prescription Drug Benefit Manual Chapter 5 Section 50.4.

Pharmacy Accreditation: CMS has also requested comments on the emerging practice of Part D sponsors and their PBMs to require "accreditation" standards in network and/or AWP contracts. The majority of regional and national infusion pharmacies, including BioScrip, are accredited by one of three organizations with well-developed peer-reviewed accreditation programs for this practice setting: the Accreditation Commission for Healthcare (ACHC), the Community Health Accreditation Program (CHAP), and The Joint Commission. The accreditation standards of these organizations reflect the specific professional standards of practice for infusion pharmacists, nurses, and for USP <797> compliant sterile compounding and has become the true community standard of care for infusion pharmacies. That being said, we also are aware that Part D Plans or their PBMs have invented their own "accreditation standards" that have not been peer reviewed or subject to independent evaluation. Similarly, we have seen Part D Plans misapply other pharmacy accreditation standards to home infusion pharmacies that simply are not applicable.

For that reason, we urge CMS to specifically prohibit Part D sponsors from requiring any accreditation requirements of home infusion pharmacies other than those of the three entities identified above. At a minimum, however, we urge CMS to prohibit Part D Plans from utilizing any accreditation standards other than those which have been developed by independent consensus based standards organizations like ACHC.

II. Application of "Pharmacy Payment Adjustments" to Drug Prices.

CMS in the proposed rule has recognized the PBMs' abuse of so-called of "pharmacy fees" which the Agency labels "pharmacy payment adjustments." These fees include both "claims processing" and "switch fees" that are assessed prior to prescription being adjudicated, as well as "post-point of sale" fees which are assessed days, weeks or even months after the prescription has been adjudicated.

To be clear, in our view there is no "adjustment" actually taking place, and there is nothing to "adjust." Rather, these fees represent PBMs efforts to extract payment from pharmacies that the PBMs are obligated to pay for dispensing medications to the PBMs' Part D Plan members. There is no other industry with which we are familiar where the entity paying for a service extracts fees from its service providers in order for the providers to get paid for their work. Yet, that is exactly what is happening here. Given the lack of any reason for these fees to exist, we urge CMS to prohibit pharmacy fees[2] outright, rather than try create some scheme to "pass them through" to the patient at the point of sale.

We do appreciate CMS's analysis of the pharmacy fee problem, and the Agency's accurate observation that the so-called "pharmacy incentive payments" have "grown faster than any other category of DIR received by sponsors and PBMs." 82 Fed. Reg. at 56419. Similarly, because the amounts exceed Plan "bid" calculations they do not help beneficiaries or the program, but instead are being misused by PBMs to contribute to plan profits." 82 Fed. Reg. at 56420. As CMS also notes, PBMs also try to mask their fees as" Quality" or "Performance" holdbacks. 82 Fed. Reg. at 56419. Yet, as CMS recognizes from its own data, the amounts of "performance" fees taken from pharmacies by PBMs "are far greater than those paid to network pharmacies after the point of sale

[2] BioScrip does not address, and takes no position, on the negotiation of rebates and discounts between PBMs and drug manufacturers, other than to agree with the Agency that these rebates should be passed on to the patient at the point of sale under one of the methodologies in the proposed rule.

(pharmacy incentive fees) for "high performance." 82 Fed. Reg. at 56426 (emphasis in original). BioScrip agrees with this assessment and it has been our experience as well – we are often forced by PBMs to forego (through a holdback) "quality" or "performance" fees that we never see repaid. We further believe the same is true of the home infusion pharmacy business overall. CMS is thus correct in its view that these "fees" are simply a way for PBMs to extract money from pharmacy that becomes PBM profit.

As noted above, we urge the Agency to adopt a regulation *prohibiting* Part D sponsors and their PBMs from assessing fees from home infusion (or any other) pharmacies. However, in the alternative, and if CMS will not prohibit these fees, we agree that the Agency should change the definition of "negotiated price" to require PDPs/PBMs remove the "reasonably determined" exception, 82 Fed. Reg. at 56426, or include a "lowest possible price" requirement, 82 Fed. Reg. at 56427.

In sum, we thank CMS for calling attention to this important issue, and we look forward to working with the Agency to curb these "DIR fee" and other PBM abuses in the Part D program.

III. Formulary Mid-Year Substitution

CMS proposes to permit mid-plan year substitution of a generic for a branded medication that was on the Plan formulary without specific advanced notice to beneficiaries or pharmacies. The proposal would also permit the elimination of coverage for the brand. BioScrip understands that the Agency proposes to rely upon a general advance notice to beneficiaries in the annual Explanation of Coverage (EOC) that such substitutions might occur during the plan year. We object to this proposal and urge the Agency to reject its adoption for three reasons.

First, the proposal eliminates a basic patient protection that is necessary to provide beneficiaries with notice of formulary changes, even if branded to generic medications, to ensure they can address the anticipated changes with their physician and prepare for prescriptions that may have a different name, appearance, or payment (including co-payment). Moreover, the immediate switch provision is particularly unfair to pharmacies, and especially home infusion pharmacies, as there may not be sufficient supply of a generic.

There is also a second, and far more important reason, to prohibit the immediate switch, which is that generics may not always be therapeutically interchangeable with a branded medication. *See, e.g.* 82 Fed. Reg. at 56415 ("we believe generic substitutions pose no threat to enrollee safety"). This is particularly true of infused antibiotics which BioScrip and other home infusion pharmacies regularly dispense. Although technically the active chemical ingredients may be interchangeable, the drug delivery platforms of generics are not always identical to their brands, posing a risk of allergic reaction and possibly anaphylactic shock to home infusion patients with immune deficiency or needing specific antibiotics. In such situations the branded medication must be available on formulary to treat the patient. BioScrip appreciates that those medications can be made available upon appeal, but if the brand is eliminated without notice it will be all the more difficult for the beneficiary to secure access to the needed medication.

Third, we suggest that the proposed regulation is not needed, as Prescription Drug Plans have numerous utilization controls, including step therapy and prior authorization, that they can

immediately deploy to steer beneficiaries to new generics that are added on formulary mid-plan year. BioScrip believes that the existing tools are more than adequate to ensure that patients in appropriate circumstances utilize less costly generics. For these reasons, BioScrip asks that the proposed regulation be withdrawn.

IV. Cara Implementation -- Exemptions to Part D Lock-in.

BioScrip welcomes the proposed regulations implementing the Comprehensive Addiction and Recovery Act of 2015 (CARA), and thanks CMS for this new regulatory initiative as part of the Proposed Rule. BioScrip, like all Americans, is very concerned about the spread of prescription drug abuse across the country and the threat it poses to our nation. We applaud your efforts and proposal, and offer one comment to improve upon the proposed regulation. More specifically, Part D beneficiaries utilizing home infusion services pose negligible risk of abusing opioids or other prescription medications from their home infusion pharmacies. Thus, we propose that home infusion pharmacies be exempt from the "lock in" provisions of the regulation.

When enacting CARA, Congress recognized that there needed to be a balance between beneficiary restrictions under the pharmacy lock-in provisions needed to reduce abuse and the risk that beneficiaries might be blocked from accessing medically necessary medications. For that reason, Congress included in the lock-in provisions an exemption for long term care and hospice settings, and gave the Secretary discretion to extend this exemption to other LTC care settings. 42 U.S.C. 1395w-10(c)(5)(C)(ii). Home infusion pharmacies should be included in the class of exempt entities.

BioScrip appreciates that the proposed exemption includes a "facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy," 82 Fed. Reg. at 56347, and we suggest that expanding this language in the Final Rule to also include home infusion pharmacies would be consistent with Congressional intent and CMS's methodology. As proposed, the exemption may not include home infusion entities, which are at minimal risk for contributing to potential beneficiary abuse. While CMS correctly acknowledges that there is always a risk of multiple pharmacies dispensing opioids or other frequently abused drugs to beneficiaries, that risk is negligible given the nature of home infusion pharmacy. As such, there would be no value in implementing a lock-in regime for drugs dispensed from home infusion pharmacies. We thus request that CMS expand the list of exempt entities to include home infusion pharmacies.

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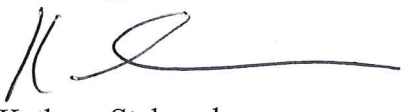
We thank you for consideration of these comments, and welcome any questions or follow up that you may have. Please feel free to contact me at (312) 350-2196 or Kathryn.stalmack@bioscrip.com if we can provide any additional information.

Sincerely,



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