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Submitted electronically via regulations.gov, Docket #: CMS-2017-0163

March 5, 2018

Mr. Demetrios Kouzoukas, Esq.
CMS Principal Deputy Administrator and Director,
Center for Medicare
U.S. Department of Health and Human Services
Room 314G
200 Independence Avenue, SW
Washington, DC 20201

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 Call Letter

Dear Mr. Kouzoukas:

On behalf of AbbVie, we appreciate the opportunity to submit comments on the "Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 Call Letter" released February 1, 2018 (hereafter, the "Advance Notice and Draft Call Letter" or the "Draft Call Letter").

At AbbVie, we strive to make a remarkable impact in the lives of patients. We are a global, research-based biopharmaceutical company with 29,000 people who are dedicated to developing and delivering a consistent stream of innovative new medicines with distinct and compelling patient benefits. With leading scientific and industry capabilities, a comprehensive approach to tackling the toughest health care challenges and a track record of achievement, we are a long-term partner in the pursuit of better health outcomes. Consistent with that mission, we are also committed to sustaining the success of the Medicare Part D Prescription Drug Benefit Program.

AbbVie appreciates the efforts of CMS to implement changes to the Medicare Advantage (MA, Part C) and Prescription Drug Benefit (Part D) programs to improve program quality, accessibility and affordability for beneficiaries in the Advance Notice and Draft Call Letter. We are particularly encouraged by efforts to ensure beneficiary access to new therapies that come onto the market just prior to – and during – the Medicare plan year. AbbVie strongly supports CMS' proposal to move the summer formulary update window to August, and to add two enhancement-only windows to the HPMS formulary files. We are concerned, however, by CMS's proposal to move forward and remove products from the formulary reference file (FRF) due to low Part D utilization without being transparent about the proposed methodology and allowing for stakeholder comment on the proposed changes.

We are also concerned with CMS's current policy regarding coverage of over-the-counter (OTC) drug products and the agency's proposal to expand this problematic program. Such a program

clearly runs counter to the intent of the Part D program to provide access to *prescription* medications, and threatens current beneficiary access to lifesaving, FDA-approved products.

We discuss both of these topics in more detail below.

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Formulary Submissions [p. 193]

AbbVie appreciates that the Draft Call Letter reiterates that the absence of a drug from the formulary reference file (FRF) does not imply that the drug is ineligible for Part D coverage. However, some plan sponsors may still decline to provide coverage for Part D-eligible drugs simply because they are not listed on the FRF. We are therefore concerned that removing drugs with low Part D utilization from the FRF may result in plan sponsors erroneously excluding certain medicines from formularies, potentially resulting in access barriers for beneficiaries. While we appreciate that CMS has made the draft CY 2019 FRF and the list of drugs targeted for deletion available for review, we urge CMS not to move forward with this proposal until it provides more detailed information on the criteria and/or thresholds used to identify drugs with low Part D utilization and to provide stakeholders with an opportunity to comment on the proposed methodology.

Next, as CMS acknowledges in the Draft Call Letter, the current summer formulary update window (late July) means that brand and generic products newly approved in late July and August are not included in plan formularies prior to the start of the plan year. As a result, beneficiaries may experience delays in accessing new, critical therapy options. Indeed, despite receiving approval well in advance of the start of the FY 2018 plan year, many important therapies were not added onto formularies – and thus were not easily accessible to Medicare beneficiaries – until several months into the plan year. As an example, AbbVie's FDA-approved MAVYRET™, the first eight-week pan-genotypic treatment for chronic hepatitis C, was approved on August 3, 2017, just days after the close of the FY 2018 summer formulary update window, and despite receiving approval nearly 2.5 months *prior* to the start of open enrollment, this critical therapy was generally not included on formularies at the start of the plan year.

We urge CMS to delay the formulary update window until as late as feasible in August, so that the formularies offered to beneficiaries during open enrollment are up-to-date and make available to seniors newly approved brand and generic products. Such a decision will still allow plans sufficient time to prepare materials well in advance of open enrollment.

In addition, CMS also proposes to add two new enhancement-only windows (one in late fall and one in January 2019) in an effort to provide beneficiaries with more up-to-date access and information within the Medicare Plan Finder system. AbbVie likewise supports this proposal, which will enhance beneficiary knowledge in selecting the best plan for their particular health needs, while also ensuring seamless access to newly approved therapies. We are particularly supportive of a late fall enhancement-only window, which will better permit beneficiaries in the midst of reviewing the 2019 plan options to select the best plan for their particular prescription drug needs. In light of the fact that many beneficiaries benefit from the approval of new, innovative therapies, ensuring that they are selecting a plan based on the most up-to-date plan

information is critical. We applaud CMS' commitment to ensuring seniors have access to all newly approved products in a more timely fashion.

Expanding the Part D OTC Program [p. 196]

In the Draft Call Letter, CMS seeks comment on adding additional flexibilities and broadening the current Part D over-the-counter (OTC) drug program. Under the current program, CMS permits Part D plans to provide OTCs as a utilization management strategy within their *administrative* cost structure with the expectation that such products offset the cost of a covered Part D drug. CMS is considering adding additional flexibilities into the OTC program, including removing the requirement that such products offset other Part D costs.

At the outset we remind CMS that the statutory definition of a Part D drug *was intended to preclude* coverage of OTC products.[1] Indeed, as CMS readily concedes in the Call Letter, "the definition of a Part D drug does not include over-the-counter drug products." Thus, Medicare prescription drug plans should not include OTCs as part of their basic benefit or supplemental coverage. This was clearly the intent of Congress in creating a *prescription drug benefit* program. OTC products often lack both the regulatory rigor and proven efficacy of their prescription drug counterparts. For example, unlike the NDA approval process for prescription drugs, the OTC monograph process: (1) contains *no* pre-market approval process and oversight occurs only on a post-marketing basis; (2) is ingredient, and not drug specific; and (3) generally requires no clinical studies nor are most products subject to label comprehension studies.[2]

Over 10 years ago, CMS created a policy allowing Part D sponsors the option to provide OTCs as a utilization management strategy *within their administrative cost structure*, but only where the use of the OTC medication would offset the use of a more costly Part D drug.[3] As CMS notes in the Draft Call Letter, currently *no* standalone prescription drug plans and only a *very few* MA-PDs offer OTCs under existing Part D policies. AbbVie strongly believes that any efforts to expand the OTC program – or increase its flexibilities – will be a detriment to the Part D program which has, since its inception, successfully provided valuable and innovative care to America's seniors.

Moreover, we are gravely concerned by any policy which will add additional utilization controls and barriers to accessing the *actual* benefit under the Part D program – prescription drugs. If given additional flexibilities, plans are likely to increase the use of step therapy and other utilization edits which require beneficiaries first to utilize (and fail) on conventional OTC therapies prior to accessing prescription drug products. Such a policy is both contrary to the intent of the statute, because it would cause Part D funds to be used for non-prescription drugs outside the administrative dollars, and places limits on access to the prescription drug that a physician has determined to be appropriate for a beneficiary. As a result, any expansion of the

[1] See Social Security Act § 1860D-2(e)(2) (excluding from coverage under the Part D benefit those drugs excluded from coverage under section 1927(d)(2), which explicitly excludes from coverage most "nonprescription drugs.")
[2] U.S. Food and Drug Administration (FDA), Differences: NDA Process and OTC Monograph Process, https://www.accessdata.fda.gov/scripts/cder/training/OTC/topic3/topic3/da_01_03_0190.htm
[3] This policy is now discussed in the Medicare Prescription Drug Benefit Manual, ch. 7, section 60.2.

OTC program could both increase Part D premiums, and result in poorer health outcomes for Medicare beneficiaries.[4]

In light of the fact that there is very little evidence that beneficiaries lack current access to OTC therapies – and given the negative consequences that such a proposed policy could have for the health of seniors – we urge CMS to refrain from adding new flexibilities to the OTC program.

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Again, thank you for the opportunity to comment on these important issues for the Part D program and enrollees. Please contact Ashley Flint if you have any questions. We look forward to continuing to work with CMS on these and other issues moving forward.

Sincerely,

Ashley Flint
Director, Federal Policy

[4] CMS notes in the Advance Notice Call Letter, "Part D sponsors cannot cover OTCs under the prescription drug benefit or as a supplemental benefit under enhanced alternative coverage." (P. 196) (Emphasis added.)