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January 25, 2019

The Honorable Alex M. Azar, II
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: CMS-4180P – Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses
83 Fed. Reg. 62152 (November 30, 2018)

Dear Secretary Azar:

The American Cancer Society Cancer Action Network (ACS CAN), appreciates the opportunity to comment on the Medicare Part C and D proposed rule. ACS CAN, the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change as well as legislative and regulatory solutions that will reduce the cancer burden.

Approximately 1.7 million new cancer cases are expected to be diagnosed in 2019.[1] Many of these new patients will likely be enrolled in the Medicare program since age is one of the most important risk factors for cancer. Therefore, changes to the Medicare Part C and D programs have a profound impact on beneficiaries who are expected to be diagnosed with cancer this year and for cancer survivors.

Increasingly drug therapies – particularly oral medications – play an integral role in cancer treatment. Cancer patients and survivors rely on drug therapies to treat their disease and side effects, and prevent recurrence. ACS CAN is committed to ensuring that all Medicare beneficiaries receive the treatment that is medically appropriate for their disease. As discussed in more detail in this letter, we are concerned that some of the policies under consideration – particularly the proposed changes related to the six protected classes – could impede beneficiaries' access to medically appropriate therapies and we urge the Department to withdraw this portion of the rule.

ACS CAN supports efforts to reduce beneficiaries' cost-sharing for their medical care. However, we are concerned with proposals that would limit access to medically-necessary treatments, because these policies can result in worse health outcomes for the beneficiary.

[1] American Cancer Society, *Cancer Facts and Figures* 2019. Atlanta: American Cancer Society; 2019. Available at https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2019/cancer-facts-and-figures-2019.pdf.

II. PROVISIONS OF THE PROPOSED REGULATION

A. Providing Plan Flexibility to Manage Protected Classes (§ 423.120(b)(2)(vii))

The Medicare Part D statute requires Part D plan sponsors to include in their formularies certain categories and classes of drugs of clinical concern, including anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection[2] (the so-called "six protected classes"). As discussed in more detail in the following sections, we have significant concerns with the proposals under consideration and urge the Administration not to finalize these proposed policies.

1. Background

ACS CAN strongly supports the preservation of the six protected classes. Since the program's inception, CMS has required all Part D plan sponsors to cover all or substantially all drugs within these classes. CMS created the six protected classes policy to ensure that beneficiaries who needed these drugs would have access to them. In fact, CMS' current Medicare Prescription Drug Policy manual clearly states that "CMS instituted this policy because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans, as well as to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations."[3]

Part D plans currently have significant flexibility within the six protected classes: We are pleased the Administration is not proposing to remove any of the six protected classes at this time. However, we disagree with the Administration's contention that changes are needed to the six protected classes policy. While Part D plan sponsors are not permitted to remove a drug within the six protected classes from their formularies, sponsors already may tier these drugs on their plans' formularies in order to have more leverage in price negotiations. Part D plans already have more restrictive formularies for drugs covered under the six protected classes relative to commercial plans,[4] suggesting that the current policy does not prevent Part D Plan sponsors from effectively managing formularies within these drug classes. In fact, research suggests that Part D generic utilization is high among drug classes within the six protected classes. According to the PEW Charitable Trusts, generic utilization for drugs within the six protected classes is higher than other drug classes (92 percent versus 84 percent).[5] The Medicare

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[2] 42 U.S.C. § 1395w-104(b)(3)(G)(iv).

[3] Centers for Medicare & Medicaid Services, *Medicare Prescription Drug Benefit Manual*, Ch. 6 – Part D Drugs and Formulary Requirements, sect. 30.2.5.

[4] Kelly Brantley, Jacqueline Wingfield, and Bonnie Washington, "An Analysis of Access to Anticonvulsants in Medicare Part D and Commercial Health Insurance Plans," Avalere Health (2013). Available at http://avalere.com/research/docs/Anticonvulsants_in_Part_D_and_Commercial_Health_Insurance.pdf (finding that on average commercial plans covered 80 percent of anticonvulsant drugs compared to Part D plans which covered on average 62 percent).

[5] The PEW Charitable Trusts, *Policy Proposal: Revising Medicare's Protected Classes Policy*, March 2018. Available at https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/03/policy-proposal-revising-medicares-protected-classes-policy.

Payment Advisory Commission (MedPAC) notes that the "protected status does not appear to affect plan sponsors' ability to encourage the use of generics."[6]

In addition, Part D plans often steer beneficiaries to lower-cost alternative drugs within the therapeutic classes through the use of formulary tier placement and through existing exceptions to the six protected classes policy. Under current policy, all drugs and unique dosage forms within the six protected classes are expected to be included, except "multi-source brands of the identical molecular structure; extended release products when the immediate-release product is included; products that have the same active ingredient or moiety; and dosage forms that do not provide a unique route of administration (e.g., tablets and capsules versus tablets and transdermals)."[7]

Excluding drugs harms beneficiaries: The preamble of the proposal suggests that Part D plans could realize greater rebates on drugs within the six protected classes if sponsors had the ability to exclude drugs from coverage.[8] However, this argument fails to take into account that allowing Part D sponsors to exclude drugs from coverage could result in beneficiaries being unable to access medically necessary therapies. When beneficiaries are denied access to medically appropriate therapies, it can result in negative health outcomes, which can increase Medicare costs (in the form of higher physician and/or hospital services to address the negative health outcomes) and result in higher beneficiary cost sharing associated with these additional services.

Potential long-term impact on research and development: We are also concerned about the long-term impact of this policy on disincentivizing pharmaceutical manufacturers to devote research into oral anti-cancer medications. Pharmaceutical manufacturers may be less likely to invest in oral anti-cancer medications if there is concern that the Medicare program would not cover the product. Oral cancer medications – such as those in the antineoplastics category – are often preferred by patients because they are more convenient and are easier to administer, particularly for beneficiaries for whom travel to outpatient treatment is onerous. Oral medications can also reduce health care expenditures (such as Medicare Part A or B services) because they often require fewer physicians' visits. Between 25 to 35 percent of therapies in the development pipeline are for oral therapies.[9] We are concerned that if CMS finalizes its policy as proposed, it could have a chilling effect on future research and development.

2. Broader use of utilization management for protected class drugs

CMS is proposing to allow Part D sponsors to use prior authorization for drugs within the six protected classes, as is done for all other non-protected categories and classes of drugs. The preamble notes that under this policy Part D sponsors could impose prior authorization requirements and could also "implement step therapy for protected class drugs or to determine use for protected class drugs indications or both, without distinguishing between new starts or existing therapies."[10] The CMS policy

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[6] Medicare Payment Advisory Commission. Report to Congress: Medicare and the health care delivery system. Improving Medicare Part D (2016), at: 191.
[7] Centers for Medicare & Medicaid Services, *Medicare Prescription Drug Benefit Manual*, Ch. 6 – Part D Drugs and Formulary Requirements, sect. 30.2.5.
[8] 83 Fed. Reg. at 62157.
[9] American Society of Clinical Oncology. Policy Brief: Parity in Coverage of Cancer Drugs. Nov. 7, 2017. Available at https://www.asco.org/advocacy-policy/asco-in-action/policy-issue-brief-parity-coverage-cancer-drugs.
[10] 83 Fed. Reg. at 62158.

would "also allow indication-based formulary design and utilization management for protected class drugs."[11]

Cancer care requires access to specific treatments: The six protected classes policy was enacted to ensure that vulnerable beneficiaries had access to all or substantially all of the therapeutically equivalent drugs to treat their diseases or conditions. Cancer care often requires specialized treatments and, in some cases, the genetic changes in a patient's tumor can determine treatment.

Many of the prescription drugs are not necessarily therapeutically equivalent to other products within the same class. For example, within the Antineoplastics class of drugs, the United States Pharmacopeia identifies 12 subclasses and 86 unique drugs.[12] One of the unique subclasses, molecular target inhibitors, contains 38 unique drugs, which are used to treat a variety of different cancers harboring specific genetic mutations. Many of these drugs are relevant to a small subcategory of patients within a single disease and are not necessarily interchangeable products appropriate for step therapy.

We also note that many beneficiaries have co-morbid conditions that require very nuanced treatment regimens. For example, one fourth of cancer patients have a diagnosis of clinical depression,[13] which may be managed with pharmaceutical interventions that may limit cancer treatment options because of drug interactions or side effects. As such, when beneficiaries are in active cancer treatment, it can be particularly challenging to manage co-morbid conditions. Imposing additional step therapy requirements on any of the six protected classes creates additional unnecessary administrative challenges for providers who are treating medically complex beneficiaries.

Disruptions in cancer care can result in negative health outcomes: Step therapy policies can lead to patients not filling their prescriptions or underutilizing medications,[14] which can have a negative impact on beneficiary adherence to medications. Prescription drug noncompliance can lead to poorer health outcomes for the beneficiary as well as increased costs to the Medicare program. In addition, studies have shown that the prior authorization process is not only complicated and labor intensive, but given the high approval rate, the requirements have not been shown to reduce medication utilization and thus simply impose unnecessary burdens on patient care.[15]

In order to increase the likelihood of a successful outcome, beneficiaries need access to cancer treatments that are as targeted as possible. Delaying cancer care – by requiring beneficiaries to undergo step therapy – is both a waste of money for the beneficiary and the program. It can also result in negative health outcomes.

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[11] Id.
[12] Unites States Pharmacopeia. USP Medicare Model Guidelines v7.0. Available at http://www.usp.org/sites/default/files/usp/document/our-work/healthcare-quality-safety/uspmmg_v7_0_cat-class.pdf.
[13] American Cancer Society, *Coping with Cancer: Anxiety, Fear, and Depression*. Available at https://www.cancer.org/treatment/treatments-and-side-effects/emotional-side-effects/anxiety-feardepression.html.
[14] Carlton RI, Bramley TJ, Nightengale B, Conner TM, Zacker C. Review of outcomes associated with formulary restrictions: focus on step therapy. Am J Pharm Benefits. 2010;2(1):50-58.
[15] Agarwal A, Freedman R, Goicuria F, Rhinehart C, Murphy K, Kelly E, Mullaney E, St. Amand M, Nguyen P, Lin NU. Prior Authorization for Medications in a Breast Oncology Practice: Navigation of a Complex Process. J of Onco Practice. 2017 13(4), e273–e282.

Prior authorization requirements are administratively onerous: In general, overuse of utilization management tools increases administrative complexity. Imposing prior authorization requirements has been shown to have a measurable burden on physician and staff time.[16] Physicians report that prior authorization is behind the majority of care delays and the administratively burdensome processes are linked to patients abandoning prescribed treatments. They indicate that large and growing amounts of their time each week, now about two business days per week on average, are devoted to processing prior authorization requests and that physicians often are required to repeat those processes for the same medication for a patient.[17] Prior authorization policies might also have significant unintended consequences for patients – taking a significant amount of time, increasing treatment discontinuities, and reducing quality of care.[18]

Formulary review process: The preamble notes that Part D plans will continue to have to abide by current formulary requirements, including CMS review of a formulary drug list to ensure its compliance with CMS' rules and regulations.[19] However, we note that with respect to existing utilization management restrictions (e.g., those applicable to drugs outside the six protected classes), CMS' analysis consists of comparing all Part D plans' formulary submissions to analyze the comparative use of utilization management tools to identify outliers.[20] We are concerned that an outlier analysis is an insufficient tool to provide oversight against potential anti-discriminatory practices. An outlier analysis is simply a test to determine if a certain plan is being more discriminatory than other plans but would not identify common discriminatory practices among plans.

Existing therapies should not be impacted: CMS is considering allowing Part D plans to impose prior authorization and step therapy requirements for both new and existing prescriptions. As discussed above, we have grave concerns with the proposal to allow Part D plans to impose prior authorization and step therapy requirements on drugs included in the six protected classes and do not support CMS imposing the requirement on new starts.

In addition, we strongly urge CMS to reject this policy for existing therapies. Requiring beneficiaries to undergo step therapy requirements after they have already been stabilized on a treatment regimen can cause disruptions to the overall success of the beneficiary's treatment and create negative treatment health care outcomes. In addition, the policy is administratively onerous on providers, who are already burdened by such requirements.

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[16] Morley C, Badolato D, Hickner J, Epling J. The impact of prior authorization requirements on primary care physicians' offices: report of two parallel network studies. J of the Am Bd of Family Med. 2013; 26(1), 93–95..

[17] American Medical Association. 2017 AMA Prior Authorization Physician Survey. Available at https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc/prior-auth-2017.pdf.

[18] Lu CY, Soumerai SB, Ross-Degnan D, Zhang F, Adams AS. Unintended Impacts of a Medicaid Prior Authorization Policy on Access to Medications for Bipolar Illness. Medical Care. Jan. 2010. Vol. 48, No. 1, pp. 4-9.

[19] 83 Fed. Reg. at 62157 (noting that "an exception from the protected class policy would not supersede our other formulary requirements in § 423.120(b)(2).").

[20] Centers for Medicare & Medicaid Services, *Medicare Prescription Drug Benefit Manual*, Ch. 6 – Part D Drugs and Formulary Requirements, sect. 30.2.7 stating that "UM restrictions will also be evaluated as part of the formulary content review. In addition to ensuring that the use of these tools are consistent with industry best practices, CMS will also compare all sponsors' formulary submissions to analyze the comparative use of UM tools. When outliers are identified, CMS will request a clinical justification that supports the use of the submitted edits."

3. New formulations

CMS is proposing to permit Part D sponsors to exclude from their formularies a protected class single-source drug or biologic product for which the manufacturer introduced a new formulation with the same active ingredient or moiety that does not provide a unique route of administration.

ACS CAN is concerned that this policy would result in beneficiaries not having access to the latest formulation of a prescription drug. We note that prescription drugs that are "extended release" differ quite substantially from an "immediate-release" version of the same drug, particularly as it relates to beneficiary adherence. Extended release drugs often are taken with less frequency than immediate-release drugs, thus improving beneficiary quality of life and increasing the likelihood of beneficiary adherence.[21]

We are also concerned that the preamble notes that the "purpose of this proposed exception is to specify that even if a new formulation of a single-source drug or biological product in the protected class becomes the only formation available, Part D sponsors could exclude it from their formularies."[22] We are particularly concerned that this proposal would deny beneficiaries access to medically-necessary, FDA-approved prescription drugs that otherwise should be covered under the Medicare program. This policy negatively harms beneficiaries for actions taken by pharmaceutical companies. Beneficiaries who are not able to be stabilized on outpatient prescription drugs are more likely to require additional medical care which would increase health care expenditures under the Medicare Part A and B programs, not only costing the beneficiary additional time and a decreased quality of life, but also needlessly increasing overall Medicare expenditures.

The preamble notes that this policy would not supersede CMS' current policy of requiring Part D plans to cover at least two drugs per therapeutic category or class. The two-drug-per-class policy is an important beneficiary protection in that it ensures Part D plans have a more robust formulary. However, as discussed in detail above, drugs within the same class or subclass can be FDA-approved to treat different diseases or conditions and thus beneficiaries need access to all drugs within these protected classes.

4. Pricing threshold for protected class drug formulary exclusions

CMS proposes, effective for plan years starting January 1, 2020, to permit Part D sponsors to exclude from their formularies any single-source drug or biological product that is a protected class drug whose price increases. Under the proposal, if a protected class drug's price increases beyond a benchmark (which CMS proposes to be the rate of inflation, defined as the Consumer Price Index for all Urban Consumers (CPI-U)), Part D sponsors would be permitted to no longer cover the drug.[23]

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[21] Ingersoll KS, Cohen J. The impact of medication regimen factors on adherence to chronic treatment: a review of literature. J Behav. Med. 2008. Jan 10. Doi:10.1007/s10865-007-9147-y; Wertheimer A, Santella TM, Finesone AJ, Levy R. Clinical and economic advantages of modern dosage forms: improving medication adherence. Center for Pharm. Health Service Res. Temple University. Available at https://www.npcnow.org/system/files/research/download/Clinical-and-Economic-Advantages-of-Modern-Dosage-Forms-Improving-Medication-Adherence.pdf.

[22] 83 Fed. Reg. at 62159.

[23] Id.

Proposal could deny beneficiaries access to therapies: While we appreciate the Administration's interest in making prescription drugs more affordable for beneficiaries, we are concerned with the proposal in its current form. If a pharmaceutical manufacturer were to increase its price for a given period beyond the corresponding CPI-U percentage for that period, a Part D plan could remove the drug from its formulary, thus denying beneficiaries coverage for the medication. Under the proposal, Part D plans could exclude the drug from their formularies for the entire plan year. CMS also requests feedback on whether plans should be permitted to exclude these drugs for all future plan years.

Allowing a drug to be excluded from a Part D plan's formulary effectively means that there would be no Medicare coverage. This proposal would be permitted regardless of whether the drug is a single-source drug (e.g., if it is the only drug that is FDA-approved to treat a specific genetic mutation for a given cancer). We are concerned that this policy is seeking to impose punitive actions against a manufacturer for price increases, but the result of the policy will harm beneficiaries who will no longer be able to access medically appropriate therapies. It should be noted that beneficiaries have no influence over the price of drugs or price changes – this policy would make beneficiaries innocent bystanders.

Proposed timing is unrealistic: CMS proposes to implement this policy effective for plan years starting on or after January 1, 2020.[24] We are concerned this timeline is too ambitious. In order to implement this policy within that timeframe, CMS would need to review and synthesize all of the stakeholder comments, make modifications to the proposed rule based on stakeholder recommendations, and acquire the necessary administrative clearance in order to release a final rule in short order (presumably prior to or concurrent with the release of the annual Part D and Medicare Advantage Call Letter). Given the controversy surrounding many of the proposed changes, it is anticipated that CMS will receive numerous detailed comments, which will further impede CMS' ability to meet the proposed timeframe.

5. Solicitation of comment for special consideration

CMS notes that its proposed changes to the six protected classes policy would not supersede existing beneficiary protections, including formulary requirements (i.e., that plans have to cover at least two drugs per category and class) and the Part D appeals and exceptions process. While we appreciate that CMS intends to retain these important beneficiary protections, we do not view these policies alone to be sufficient to ensure beneficiary access.

Formulary requirements: Under the statute, Part D plans have to cover at least two drugs per category and class. While this policy provides a strong protection, we note that some classes encompass multiple drugs that are intended for different, non-overlapping purposes. For example, the Molecular Target Inhibitor class contains approximately 40 drugs, that are designed to disrupt the growth of a tumor. Different patients have different receptor status and will respond only to certain molecular target inhibitors. These drugs are FDA-approved for different indications, such as lung cancer and breast cancer. Simply allowing a Part D sponsor to choose two drugs within a class as robust as the Molecular Target Inhibitors could allow a plan the ability to discriminate against beneficiaries with certain types of cancer.

Medicare Part D appeals process: The Medicare Part D appeals and exceptions process provides insufficient protection to ensure that beneficiaries would have access to medically appropriate therapies under the proposal. As the Medicare Payment Advisory Commission (MedPAC) has noted, there exists

[24] Id.

widespread frustration among stakeholders – including beneficiary advocates, prescribers, plan sponsors, and CMS – regarding the existing process.[25] The process can be time consuming, frustrating, and burdensome for some beneficiaries.[26]

It can also be challenging to determine how often beneficiaries simply choose not to fill a prescription at the pharmacy counter compared to those who decide ultimately to file an appeal. MedPAC has also found that four percent of Part D plan prescriptions are rejected at the pharmacy primarily for formulary status issues. Nine percent of these rejections are appealed, with 64 percent of the requests ultimately being adjudicated in favor of the beneficiary.[27]

We are gravely concerned that finalizing the policies as proposed would further burden this process, thus resulting in more frustration for beneficiaries. This is particularly concerning given that the proposal does not make mention of any additional CMS resources (such as additional staff or appropriations) to ensure that beneficiaries who need access to drugs within the protected classes are able to obtain their medications in a timely manner.

B. Prohibition Against Gag Clauses in Pharmacy Contracts (§ 423.120(a)(8)(iii))

CMS proposes to make Part D regulations consistent with recently enacted statute and to prohibit a Part D sponsor from penalizing or prohibiting a pharmacy from informing a Part D beneficiary that their cost-sharing associated with a prescription drug may be higher than the cash price (known as a pharmacy "gag clause").

ACS CAN supports the prohibition and removal of pharmacy gag clauses in all contracting between pharmacies, insurance plans, and (where applicable) pharmacy benefit managers. Removing gag clauses will allow pharmacists/pharmacies to have the opportunity to have a more open dialogue regarding questions the patients may have about their prescription drugs.

D. Part D Explanation of Benefits (§ 423.128)

CMS requires Part D sponsors to provide beneficiaries with a written explanation of benefits (EOB) and a notice of the benefits in relation to the initial coverage limit and out-of-pocket threshold for the given year. CMS is proposing to also require Part D plans to include in the EOB information about negotiated price changes and lower-cost therapeutic alternatives.

ACS CAN supports providing beneficiaries with more information on lower-cost alternatives. Providing additional information to beneficiaries can be helpful to foster an open dialogue between the beneficiary and their provider to determine their best treatment. We are pleased this proposal provides information to beneficiaries without mandating that beneficiaries switch to a lower-cost alternative, which may not be medically indicated. In order to improve the usefulness of this notice, we urge CMS to ensure that the information is individualized to the beneficiary, to the extent possible, and does not simply reflect lower-cost alternatives to an average sample population.

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[25] Medicare Payment Advisory Commission, *Report to Congress: Medicare Payment Policy*, status report on the Medicare prescription drug program (Part D), March 2017 at 421.
[26] Id.
[27] Medicare Payment Advisory Commission, *Report to Congress: Medicare Payment Policy*, status report on the Medicare prescription drug program (Part D), Online appendixes, March 2018.

E. Medicare Advantage and step therapy for Part B drugs (§§ 422.136, 422.568, 422.570, 422.572, 422.584, 422.590, 422.618, 422.619)

On August 7, 2018, CMS announced a new policy that would allow Medicare Advantage (MA) plans to impose utilization management tools such as step therapy for Part B drugs.[28] CMS now proposes to codify this policy. ACS CAN has serious concerns with this policy.

Step therapy is not always appropriate: Drugs within the same therapeutic class can be used to treat different diseases and conditions. Therefore, step therapy within a given class of drugs is not always appropriate. Cancer treatments are often prescribed based on a variety of factors, including the type of cancer, specific tumor mutations (if any), and the stage of diagnosis. Individuals undergoing cancer treatment often need timely access to prescription drugs and a delay could negatively impact a patient's prognosis. Requiring beneficiaries to undergo step therapy can delay their access to medically-appropriate therapies and result in additional costs for both the beneficiary and the program.

Proposed safeguards are insufficient to ensure beneficiary protection: Proposed §422.136(a) would allow MA plans to apply step therapy (1) only to new administration of Part B drugs (using at least a 108 day look-back period); (2) if the MA plan establishes procedures to educate and inform providers and enrollees concerning the step therapy requirements; and (3) before implementing a Part B step therapy program, the MA plan must ensure that such policy has been reviewed and approved by the MA organization's pharmacy and therapeutic (P&T) committee. For the reasons discussed in more detail below, we do not believe these guardrails are sufficient.

Imposing step therapy requirements on new therapies: While we have significant concerns with this proposed policy, we appreciate that CMS' proposal would only apply to treatment therapies that are new to the patient and would not require beneficiaries to have to undergo step therapy requirements on an annual basis. We strongly oppose extending this policy to existing therapies as this would be unnecessarily administratively burdensome on providers and beneficiaries.

Proposed look-back period is insufficient: CMS is proposing to require MA plans to have a look-back period of 108 days, similar to the Part D transition policy, to determine if the beneficiary is actively taking a Part B medication. This look-back period would also apply to beneficiaries who are newly enrolled in an MA plan (whether the beneficiary is newly eligible to Medicare or switched plans). While we appreciate CMS' intention to provide a look-back period, we do not believe the 108-day period is sufficient time and urge CMS to remove the limitation on the look-back period. If CMS were to finalize this policy, we believe beneficiaries who have previously undergone step therapy protocols should not be required to undergo such protocols again.

Education and outreach: We believe education and outreach is vitally important for any new policy that impacts beneficiaries, but we are concerned that the proposed policy may be insufficient. The preamble notes that MA plans must disclose that Part B drugs may be subject to step therapy requirements in the plan's Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) documents.[29] The ANOC can be a useful tool to inform beneficiaries of changes to the MA plan prior to

[28] Centers for Medicare and Medicaid Services. Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage. Aug. 7, 2018. Available at https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf.
[29] 83 Fed. Reg. at 62169.

the Medicare annual election period. However, many beneficiaries do not fully read and comprehend their annual ANOC and thus this tool may not be an appropriate tool in which to fully educate beneficiaries about this policy. In addition, we urge CMS to clarify that the ANOC and EOC should not only note which drugs may be subject to step therapy requirements, but that CMS also include information on what step therapy is and how beneficiaries and their providers can seek an exception to the policy.

Moreover, MA plans that chose to impose step therapy requirements would presumably have to disclose all Part B drugs that are subject to step therapy requirements. This policy could significantly increase the length and complexity of the ANOC, which would not only cause beneficiary confusion, but could also reduce the overall usefulness of the ANOC. Even if a beneficiary were to read their ANOC, the information provided would only be useful to a beneficiary who was currently taking a specific Part B drug that was the subject of step therapy requirements. The ANOC would not be a useful tool to a beneficiary who was not yet taking a Part B drug that could be the subject of step therapy requirements.

In addition, CMS proposes to require MA plans to establish policies and procedures to inform providers and enrollees about plan policies regarding step therapy requirements. It is not clear whether CMS intends to allow MA plans to use only the ANOC and EOB processes to inform beneficiaries of a step therapy requirement. As discussed previously, we do not believe these mechanisms alone constitute sufficient beneficiary education. If CMS were to finalize this policy, we strongly urge that CMS – not the plans – develop and test template materials. CMS should provide an opportunity for public input and feedback on those template materials and in that process, CMS should also identify and review best practices of health plans that have implemented step therapy policies for other populations.

Use of P&T committee: CMS is proposing to require MA Plans to use a Pharmacy & Therapeutics (P&T) committee to review and approve any step therapy policies and procedures. We urge CMS to require MA plans to follow the same P&T committee requirements as exists for Part D plans.

Any step therapy program must be based on evidence, and not merely imposed as a cost-saving mechanism. We strongly urge CMS to require that MA plans with step therapy programs be required to have P&T committees and that these committees must approve any step therapy protocols.

Appeals: CMS is proposing that requests for Part B drugs, including Part B drugs subject to step therapy, be processed under the same adjudication timeframes as is used in the Part D program. We note that the adjudication timeframes are shorter under Part D than under Part B and appreciate CMS' proposal.

However, we note that additional improvements are warranted for the underlying Part B adjudication process. According to a recent HHS Office of Inspector General report, Medicare Advantage Organizations overturned 75 percent of their own denials during 2014-2016, suggesting that some MA plans were initially denying services that should have been provided.[30] Before CMS institutes this policy of allowing MA plans to use step therapy programs, we strongly urge CMS to review the existing Part B appeals structure and address any deficiencies that hinder beneficiaries' access to covered services.

[30] U.S. Department of Health and Human Services Office of Inspector General. *Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials.* Sept. 2018 (OEI-09-16-00410).

F. Pharmacy price concessions in the negotiated price (§ 423.100)

3. Considered regulatory changes to the definition of negotiated price (§ 423.100)

CMS is requesting feedback on a proposal to change the definition of "negotiated price" to include all pharmacy price concessions received by the Part D plan for a covered Part D drug. Under the proposed rule, CMS would require that all pharmacy price concessions be included in the negotiated price. Previously CMS regulations had exempted from the definition contingent pharmacy payment adjustments that could not reasonably be determined at the point of sale.

ACS CAN supports CMS' proposed changes to the definition of "negotiated price." The negotiated price is used to determine Part D plan, beneficiary, manufacturer (e.g., coverage gap liability), and government liability over the course of the year. Beneficiary cost-sharing is generally calculated as a percentage of the negotiated price. As noted in the preamble, when pharmacy price concessions are not reflected in the negotiated price at the point of sale, beneficiary cost-sharing increases.[31] Beneficiaries whose cost-sharing is calculated as a co-insurance, rather than a fixed co-payment, are particularly impacted by this change.

CONCLUSION

On behalf of the American Cancer Society Cancer Action Network we thank you for the opportunity to comment on the proposed changes to the Medicare Part C and D programs. As stated above, we have serious concerns with the proposed changes to the Medicare Part D six protected classes and urge the Administration to not finalize the policy as proposed. If you have any questions, please feel free to contact me or have your staff contact Anna Schwamlein Howard, Policy Principal, Access and Quality of Care at Anna.Howard@cancer.org or 202-585-3261.

Sincerely,

Christopher W. Hansen
President
American Cancer Society Cancer Action Network

[31] 83 Fed. Reg. at 62176.