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January 16, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4182-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

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 Proposed Rule
82 Fed. Reg. 56336 (November 18, 2017)

Dear Administrator Verma:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the proposed rule implementing policy and technical changes to the Medicare Part C and D programs. ACS CAN is the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society and supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. As the nation's leading advocate for public policies that are helping to defeat cancer, ACS CAN ensures that cancer patients, survivors, and their families have a voice in public policy matters at all levels of government.

ACS CAN offers the following comments on the proposed rule:

A. Supporting Innovative Approaches to Improving Quality, Accessibility, and Affordability

1. Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions

CMS proposes to implement the statutory provisions of the Comprehensive Addiction and Recovery Act of 2016 (CARA), which provides new authority for Medicare Part D plan sponsors to implement a drug management program that could limit access to coverage of opioids for beneficiaries deemed at-risk for misuse or abuse. CMS proposes a framework for Part D sponsors which builds on an existing Part D Opioid Drug Utilization Review (DUR) Policy and the Overutilization Monitoring System (OMS). We offer the following specific recommendations.

c. Integration of CARA and the Current Part D Opioid DUR Policy and OMS

2. Proposed Requirements for Part D Drug Management Programs (§§423.100 and 423.153)

(i) Definitions (§423.100)

(A) Definition of "Potential At-Risk Beneficiary" and "At-Risk Beneficiary" (§423.100)

CMS proposes to retrospectively review beneficiary data to identify individuals who are potentially at risk for opioid misuse or abuse. Beneficiaries would be flagged as "potential at-risk" beneficiaries if they are 1) identified through the clinical guidelines discussed below or 2) identified as "potential at-risk" by the Part D plan in which they were most recently enrolled. After conducting case management and obtaining agreement from the patient's providers (in most cases), a Part D plan may change the beneficiary's status to "at-risk" for misuse or abuse of such frequently abused drugs under a Part D plan sponsor's drug management program.

CMS exempts beneficiaries with a cancer diagnosis. However, the determination of such an exemption is not made until after the beneficiary is first flagged as potentially at risk. Presumably this will result in many cancer patients being initially designated as potentially at risk, only to have the designation removed later once they are determined to be exempt because of their cancer diagnosis. It is unclear whether plans are able to use their own claims analysis to easily determine whether a beneficiary is exempt, or whether they must determine the exemptions through case management – a time- and resource-intensive process. While in most cases; a cancer patient who is flagged as potentially at-risk, but then determined to not be at-risk because of a cancer diagnosis; would not see any change to their healthcare or access to treatments. However, we are concerned this will not universally be the case. Cancer patients whose providers are not responsive to plan case management efforts could potentially receive notices or see access restrictions even though the patient should be exempt. There is also the potential for clerical errors and administrative mistakes and delays that could result in a cancer patient getting confusing notices or access restrictions.

Therefore, ACS CAN strongly encourages CMS to explore ways to identify exempted beneficiaries earlier in the process. CMS implies that it is relatively easy to identify cancer diagnoses in CMS data. If that is the case, we urge CMS to add the "not an exempted beneficiary" criteria to the definition of a "potential at-risk" beneficiary, so that such exemptions will be identified earlier and access restrictions will not be imposed on anyone who is rightfully exempted from the policy. This will have the added benefit of putting less burden on plan sponsors, who presumably have to conduct case management for everyone identified as potentially at-risk, and providers who must participate in such case management.

(B) Definition of "Frequently Abused Drug", "Clinical Guidelines", "Program Size", and "Exempted Beneficiary" (§423.100)

Clinical Guidelines and Program Size: CMS proposes that potential at-risk beneficiaries and actual at-risk beneficiaries be identified by CMS or the Part D sponsor using clinical guidelines that: (1) are developed with stakeholder consultation; (2) are based on the acquisition of frequently abused drugs from multiple prescribers, multiple pharmacies, the level of frequently abused drugs, or any combination of these factors; (3) are derived from expert opinion and an analysis of Medicare data; and (4) include a program size estimate.

For plan year 2019, CMS proposes using the clinical guidelines: 1) use of opioids with an average daily Morphine Equivalent Dosing (MME) greater than or equal to 90 mg for any duration during the most recent six months and either 2) four or more opioid prescribers and four or more opioid dispensing pharmacies OR 3) six or more opioid prescribers, regardless of the number of opioid dispensing pharmacies. CMS provides several reasons for using these criteria, including conformance with the *CDC Guideline for Prescribing Opioids for Chronic Pain*,[1] and the fact that Plan D sponsors already have experience with the criteria. CMS may propose different clinical guidelines in future years.

ACS CAN encourages CMS to retain the requirement that the guidelines be developed with stakeholder consultation. However, we also encourage CMS to modify its second criteria. By including the phrase "or any combination of these factors," it appears that in the future CMS could implement clinical guidelines that use "level of frequently abused drugs" as an independent, sole factor in designating a beneficiary as at-risk – regardless of the presence of other criteria. A prescription for a high dose of opioids should not be considered an automatic risk factor for misuse and abuse without significant high-quality evidence showing that it is an independent risk factor regardless of individual patient characteristics or other risk criteria. Patients being treated for cancer, requiring palliative care, or those at the end of life often do require high doses of these drugs. Including a high dose of drugs as the only criteria in clinical guidelines would likely result in an unmanageably large program size, as well as unduly impact patient access. We encourage CMS to delete "or any combination of these factors" in this definition, or clarify in another way that multiple factors must be used.

Despite this concern about the general criteria for clinical guidelines, ACS CAN does support the clinical guidelines proposed for plan year 2019. We believe these guidelines are appropriately conservative in flagging beneficiaries who are truly at risk for misuse or abuse of opioids without also flagging other beneficiaries not at risk. Including beneficiaries who have received prescriptions for opioids from four or more prescribers or pharmacies would identify beneficiaries who are likely trying to game the system. It would also flag beneficiaries who are potentially being harmed by a lack of care coordination. We encourage CMS to adopt these clinical guidelines as written for plan year 2019, and specifically to retain the requirement that both criteria (high dose of opioids AND multiple prescribers and/or pharmacies) are met for a beneficiary to be designated as potentially at risk.

Additionally, ACS CAN would like to call CMS' attention to a related issue that may result in an increasing number of beneficiaries being unduly flagged as potentially at risk. In August 2017, the U.S. Drug Enforcement Agency (DEA) proposed to reduce the amount of controlled substances, including opioids, manufactured in the U.S. by twenty percent in 2018.[2] The agency is being strongly encouraged to make even bigger reductions.[3] Increasing such restrictions on manufacturing may eventually result in shortages – meaning some pharmacies might not have enough supply to fill beneficiaries' opioid

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[1] https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.
[2] U.S. Drug Enforcement Agency. "DEA proposes reduction to amount of controlled substances to be manufactured in 2018." August 4, 2017. https://www.dea.gov/divisions/hq/2017/hq080417.shtml.
[3] "Durbin Presses DEA Administrator To Lower 2018 Opioid Quotas." August 3, 2017. https://www.durbin.senate.gov/newsroom/press-releases/durbin-presses-dea-administrator-to-lower-2018-opioid-quotas. See also STAT News. " Pressure builds on the DEA to stem the supply of prescription drugs, but at what cost?" December 18, 2017. https://www.statnews.com/2017/12/18/prescription-drug-supply-dea/?utm_source=STAT+Newsletters&utm_campaign=cd5ad602b3-MR&utm_medium=email&utm_term=0_8cab1d7961-cd5ad602b3-149667153.

prescriptions. If cancer patients or other patients in pain cannot fill an opioid prescription at their regular pharmacy, they are likely to go to a different pharmacy that does have the drug in stock. If shortages become severe, patients who legitimately need to fill their opioid prescriptions may appear to look like they are "pharmacy shopping," and be flagged as potentially at-risk. ACS CAN encourages CMS to work with the DEA to ensure that beneficiaries are able to maintain their access to legitimately needed drugs, and to actively monitor this situation in light of these criteria and make course-corrections as needed. In particular, new data may need to be added in the identification process to indicate that a patient used a new pharmacy because the old one was out-of-stock, and therefore should not be counted as having met the clinical guidelines for potentially at-risk.

Exempted Beneficiary: CMS proposes three types of beneficiaries be exempted from "at-risk" status (and therefore the consequent potential for access restrictions). These includes enrollees who: 1) have elected to receive hospice care; 2) are a resident of a long-term care or other facility for which frequently-abused drugs are dispensed for residents through a contract with a single pharmacy; or 3) have a cancer diagnosis. The hospice and long-term care facility exemptions are required by CARA. CMS is proposing to add the cancer exemption based on stakeholder support, the ease by which plan sponsors are able to identify cancer diagnoses, and the fact that the current drug utilization review program already includes this exemption.

ACS CAN requests CMS clarify two aspects of this exemption. First, it is implied, but not explicitly stated, that plan sponsors identify whether potentially at-risk enrollees qualify for this cancer exemption in the current program, rather than CMS identifying beneficiaries with a cancer diagnosis. As previously stated, ACS CAN encourages CMS to explore the possibility of the designation being made at the CMS-level. This would avoid cancer patients being flagged as potentially at-risk, make the size of the lists of potentially at-risk enrollees more manageable, and result in the cancer exemption being applied uniformly across all plan sponsors. At the very least, we request confirmation in the final rule regarding which entity is required to identify the cancer diagnosis.

ACS CAN also requests clarification on the exact definition of this exemption. The proposal simply states an enrollee is exempt if he or she "has a cancer diagnosis." It is unclear whether the exact definition of "cancer diagnosis" is left up to the plan sponsor, or whether all plan sponsors are required to use the same definition. ACS CAN encourages CMS in its final rule to establish a standard definition that all plan sponsors must use – this will prevent disparate application, access issues, and opportunities for discrimination. We also encourage CMS to answer the following questions:

- Does the cancer diagnosis have to have occurred within a certain timeframe, or would any cancer diagnosis on record count, regardless of when the diagnosis was made? ACS CAN encourages CMS to not place a time limit on cancer diagnosis, because many cancer survivors continue to experience pain many years after treatment.
- How will CMS/plan sponsors identify a cancer diagnosis that may have occurred before the enrollee became a Medicare beneficiary? How will a plan sponsor identify a cancer diagnosis that may have occurred while a beneficiary was enrolled in a different plan?
- Do cancer diagnoses of all sites (e.g., breast cancer, skin cancer, etc.) and all stages (e.g., stage 0 through stage IV) qualify an enrollee for the exemption?

In its proposal, CMS specifies that it has not included an exemption for beneficiaries who are receiving palliative care, end-of-life care, or for other specific populations of patients. CMS states that these other

exemptions have not been included because they do not align with the current, previously implemented program; and that other patient populations cannot be determined administratively through CMS data, and therefore such exemptions would be harder to operationalize.

Many cancer patients need palliative care, and ACS CAN is a strong supporter of increasing access to such care for cancer patients and others with serious or chronic illness. Pain mitigation involving treatment with opioids is often part of palliative care, and therefore we support measures that will prevent palliative care patients from encountering barriers to their proper treatment. However, ACS CAN agrees with CMS that most, if not all, patients receiving palliative care who do not already fall under other exemptions would have their potential at-risk status removed during case management, and would likely not see any access restrictions. For a newly revamped program, it is reasonable for CMS to not include multiple new exemptions with which the agency and plan sponsors have no experience. However, ACS CAN encourages CMS to continue considering a palliative care exemption, and work towards operationalizing this exemption. As palliative care by definition includes care coordination, patients working with a palliative care provider are not likely to be at risk for misuse or abuse of opioids – and all stakeholders would benefit from finding a way to exempt these patients.

(vii) Beneficiary Notices and Limitation of Special Enrollment Period (§§423.153(f)(5), 423.153(f)(6), 423.38)

Currently, dually-eligible beneficiaries and those eligible for low-income subsidies (LIS) are able to use special enrollment periods (SEPs) year-round to change Medicare Part D plans, so that these low-income individuals are not stuck in a plan with inadequate drug coverage. CMS notes that "more than 76 percent of all beneficiaries estimated to be potential at-risk beneficiaries are LIS-eligible individuals," and that these individuals may now or in the future use SEPs to change plans and avoid impending opioid access limitations. Therefore, CMS proposes to make the LIS SEP unavailable for potential at-risk beneficiaries and at-risk beneficiaries.

The SEPs available to LIS beneficiaries are important for maintaining access to treatment for low-income cancer patients. Unless patients are newly diagnosed with cancer right before or during open enrollment, cancer patients in active treatment are unlikely to have shopped for their Part D plan based on their need for cancer treatments. This can result in a cancer patient being locked in to a Part D plan that does not adequately cover their drugs – and this is of particular concern to patients with very low incomes, who cannot afford high out-of-pocket costs for their medications.

We recognize the high prevalence of beneficiaries potentially at-risk for opioid misuse and abuse in the LIS population. While we urge CMS to be cautious in assuming that the majority of these beneficiaries are intentionally using the LIS SEP to game the system without evidence showing such an effect, we also recognize the need for this policy. We encourage CMS to ensure this change does not have unintended consequences. We request CMS clarify that the SEP is only removed for LIS beneficiaries once the plan sponsor has completed case management activities, including prescriber agreement. The proposed language is not entirely clear on this point, as it states that the SEP is "not available to potential at-risk enrollees." Because (as discussed earlier) the exemptions are not applied immediately, applying this limitation to all enrollees designated "potential at-risk" would remove the SEP for a much larger population than intended. ACS CAN urges CMS to clarify this sequence of events so that properly exempted enrollees do not lose their access to the LIS SEP.

Furthermore, we urge CMS to make a provision for LIS beneficiaries who lose access to their SEP, but need access to non-opioid drugs. For example, if an LIS beneficiary is determined to be at-risk and loses an SEP and is later diagnosed with a different chronic condition that requires medication not on the beneficiary's current formulary. The beneficiary in this example is unable to switch to a new plan to gain access to the needed drug because of this policy. We urge CMS in its final rule to specify that such a beneficiary would be given special consideration when submitting an appeal to their current plan to gain coverage of necessary non-opioid drugs – in light of the fact that they cannot switch plans to gain adequate coverage that way.

We also urge CMS to make the loss of the LIS SEP for at-risk beneficiaries appealable, as an at-risk beneficiary's other non-opioid-related conditions may justify the using of an SEP. We note that while this proposal stipulates an appeals process for beneficiaries wishing to appeal their at-risk status, CMS states that "while an LIS SEP under §423.38 would be restricted at the time of the beneficiary as identified as potentially at-risk under proposed §423.100, the loss of such an SEP is not appealable under section 1860D-4(h) of the Act."[4] We encourage CMS in its final rule to clarify whether the loss of an LIS SEP would be appealable in any way, and urge CMS to make a provision for beneficiaries who may need access to this SEP despite their at-risk status.

(viii) Provisions Specific to Limitations on Access to Coverage of Frequently Abused Drugs to Selected Pharmacies and Prescribers (§§ 423.153(f)(4), 423.153(f)(9), 423.153(f)(10), 423.153(f)(11), 423.153(f)(12), 423,153(f)(13))

(A) Special Requirement To Limit Access to Coverage of Frequently Abused Drugs to Selected Prescriber(s) (§ 423.153(f)(4))

In this section, CMS describes specific rules around plan sponsors implementing prescriber lock-ins for at-risk beneficiaries. Once a beneficiary is locked-in to a prescriber, it is unclear whether CMS intends exceptions to be made in emergency situations, for example if the beneficiary were discharged from an emergency department setting with a medically-necessary prescription for opioids. ACS CAN encourages CMS to clarify any relevant exemptions for emergencies.

(B) Selection of Pharmacies and Prescribers (§§ 423.153(f)(9), 423.153(f)(10), 423.153(f)(11), 423.153(f)(12), 423.153(f)(13))

CMS establishes a "reasonable access" standard regarding the pharmacy lock-in option it proposes to add for plan sponsors to use with at-risk enrollees.

ACS CAN notes that if DEA restricts the supply of opioids such that pharmacies begin running out of stock, we are concerned that patients will have to shop around for pharmacies that have their needed drugs in stock. We note that as currently written, there is no exemption to the pharmacy lock-in rules accounting for the situation of the designated pharmacy being out-of-stock. While such a problem could presumably be resolved through an appeals process, such processes do not move quickly enough for patients in severe pain. We encourage CMS to establish an exemption or some type of timely process to account for potential opioid stock shortages as part of the reasonable access standard, or elsewhere in the final rule.

[4] 82 Fed. Reg at 56,357.

2. Flexibility in the Medicare Advantage Uniformity Requirements

CMS notes that it is considering issuing future guidance that would allow MA Organizations to reduce cost-sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductible for enrollees that meet specific medical criteria – provided that the MA Organization treats similarly situated enrollees the same. In the preamble CMS cites as an example of this flexibility the ability of an MA Organization to offer diabetic enrollees zero cost-sharing for endocrinologist visits. CMS notes that it intends to review benefit designs to ensure they are in compliance with existing non-discrimination requirements.

ACS CAN supports CMS' policy to allow MA Organizations greater flexibility to provide their enrollees with reduced cost-sharing and/or additional benefits. We urge CMS to require that any supplemental benefits and/or reduced cost-sharing policies are evidence-based. For example, this policy could be used to encourage MA Organizations to cover more secondary preventive services and other services that promote prevention. Secondary prevention – i.e., preventing cancer reoccurrence, exacerbation of symptoms during treatment, or treatment complications – is also extremely important in improving health, outcomes, and reducing costs. Counseling and programs for weight management, physical activity and nutrition can not only prevent cancer, they can also prevent cancer reoccurrence, and help cancer patients currently in treatment manage their symptoms.

We also urge CMS to carefully monitor all programmatic changes imposed by MA Organizations under this new flexibility. In addition, we note that significant changes to the benefit design could increase beneficiary confusion, particularly as it relates to marketing materials provided during the annual election process. CMS should pay particular attention to any policies that would result in higher beneficiary cost-sharing as well as any policies that could be construed to provide a more favorable risk selection.

3. Segment Benefits Flexibility

CMS is proposing to allow MA plan segments (e.g., county-level portion of a plan's overall service area) to vary by benefits, in addition to varying by premium and cost-sharing; as long as the benefits, premium, and cost-sharing are uniform within each segment of the MA plan's service area. Current policy allows MA plans to have different premiums and cost-sharing amounts.

ACS CAN urges CMS not to adopt the proposed policy because it would be potentially confusing to beneficiaries because it would be difficult for them to know what, if any, benefit changes were made to the plan offerings in their service area. We question how the benefit information would be communicated to beneficiaries as they are making their plan selections. At the very least, we urge CMS to ensure that no MA Organization would be permitted to vary its benefit design within a service area until CMS has had an opportunity to review the revised plan design to ensure that the variation does not violate any federal antidiscrimination requirements.

6. Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review (§§ 422.254 and 422.256)

CMS proposes to eliminate the requirement that MA plans must be meaningfully different. The preamble notes that this proposal is limited to MA plans and is not intended to apply to stand-alone Part D Plans (PDPs).

ACS CAN appreciates CMS' intention "to improve competition, innovation, available benefit offerings, and provide beneficiaries with affordable plans that are tailored for their unique health care needs and financial situation."[5] However, we do not believe this proposed change is necessary. As CMS noted in a release in advance of the 2018 open enrollment period, the "number of Medicare Advantage plans available to individuals to choose from across the country is increasing from about 2,700 to more than 3,100 – and more than 85 percent of people with Medicare will have access to 10 or more Medicare Advantage plans."[6] This data indicates that MA plan choices are already very robust and that the addition of more plan options that vary in non-significant ways could add to the quantity, but potentially not the quality, of meaningfully different plan options.

In addition, we are concerned that eliminating the meaningful difference requirement will make it more challenging for Medicare beneficiaries to choose a plan that best meets their needs because beneficiaries will have a hard time differentiating between the plans based on relevant information. Research has shown that too many choices in MA plan offerings can be overwhelming to beneficiaries.[7] Some have suggested limiting MA plan choices to more meaningful options.[8]

7. Coordination of Enrollment and Disenrollment Through MA Organizations and Effective Dates of Coverage and Change of Coverage (§§ 422.66 and 422.68)

CMS proposes to amend § 422.66(d)(5) and related subregulatory guidance to create a new "opt in" election process that would be available to all MA Organizations for the MA enrollments of their commercial, Medicaid or other non-Medicare plan members. This new policy would allow MA Organizations to accept enrollment requests in the month immediately preceding the month in which the beneficiary is entitled to both Part A and B.

ACS CAN shares CMS' interest in making enrollment as easy as possible for those who become eligible for the Medicare program. However, we are concerned that the proposed policy would unfairly steer newly-eligible beneficiaries into particular plan offerings without regard to whether those products are in the newly-eligible beneficiaries' best interest.

The Medicare initial enrollment period is an opportunity for newly-eligible beneficiaries to review all their Medicare options – including whether to enroll in a Medicare Advantage plan or whether to choose traditional fee-for-service. Once this initial decision is made, the beneficiary has limited options available to switch to a different Medicare option. For example, a beneficiary who fails to enroll in a Medigap plan after his/her Medigap Open Enrollment Period may be precluded from purchasing a policy in the future or may have to pay more for coverage.[9]

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[5] 82 Fed. Reg. at 56,363.
[6] Centers for Medicare & Medicaid Services (2017). *Medicare offers more health coverage choices and decreased premiums in 2018* [Press Release]. Retrieved from https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-09-29.html.
[7] Bertko J, Ginsburg PB, Lieberman S, Trish E, Antos J. *Medicare Advantage: Better information tools, better beneficiary choices, better competition*. USC-Brookings Schaeffer Initiative for Health Policy. Nov. 2017. Retrieved from https://www.brookings.edu/wp-content/uploads/2017/11/ma-consumer-reforms.pdf.
[8] Id.
[9] Centers for Medicare & Medicaid Services. *Medicare & You 2018*. Retrieved from https://www.medicare.gov/Pubs/pdf/10050-Medicare-and-You.pdf.

In addition, the proposed policy is unclear on the extent to which this policy pertains to an MA Organization that offers more than one plan offering. For example, it is not clear whether the MA Organization would be required to provide information to the newly-eligible beneficiary regarding all products offered by the MA Organization, or whether the MA Organization can steer a newly-eligible beneficiary to a specific product offering. If this proposal is finalized, we urge CMS to include a notice requirement triggered upon the individual's enrollment request that advises the individual of the consequences of a plan choice (e.g., limitation on future Medigap enrollment) and alternative choices available to the beneficiary (e.g., enrollment in fee-for-service Medicare, other MA plan choices, and Part D plan choices).

It is also unclear how a beneficiary's right to enroll in a Part D plan would be impacted. While a majority of MA Organizations offer MA products with a Part D plan option (MA-PDPs), not all MA Organizations offer a Part D benefit. We would be concerned with an MA Organization being permitted to steer a beneficiary to enroll in a particular Part D plan (or MA-PDP) given the wide variation in formularies offered by PDPs and MA-PDs.

9. Part D Tiering Exceptions (§§ 423.560, 423.578(a) and (c))

CMS proposes to base a beneficiary's eligibility for a tiering exception on the lowest applicable cost-sharing for the tier containing the preferred alternative for the treatment, rather than the name of the tier. In addition, CMS is proposing to codify that cost-sharing for an approved tiering exception request is assigned to the lowest applicable tier when preferred alternatives sit on multiple tiers.

ACS CAN supports CMS' proposal, which seeks to provide clarification for tiering exemptions when Part D plan sponsors have drug tiers containing a mixture of generic and non-preferred drugs.

10. Establishing Limitations for the Part D Special Election Period (SEP) for Dually Eligible Beneficiaries (§ 423.38)

Under current policy, dually-eligible beneficiaries have an open-ended special enrollment period (SEP) and may enroll or disenroll from a Part D plan at any time during the plan year. CMS now proposes to limit dually eligible beneficiaries and those who meet the definition of an at-risk beneficiary to only one SEP per calendar year. Beneficiaries who were assigned a plan by CMS would be permitted to use the SEP before the plan election becomes effective or within two months of their enrollment in the plan.

ACS CAN urges CMS not to adopt the proposal at this time. The current policy of allowing dually-eligible beneficiaries with an open-ended SEP allows these beneficiaries the opportunity to switch plans if their current plan undergoes a mid-year formulary change. We are concerned that limiting these beneficiaries' opportunity to switch plans – particularly in light of other proposals to allow Part D plans greater flexibility in adopting mid-year formulary changes – could prove harmful to these vulnerable beneficiaries.

If CMS decides to proceed with this proposal, it should allow dually-eligible beneficiaries the right to file an appeal to switch plans in instances where their Part D plan has made a material change (such as to its formulary or to its pharmacy network) during the plan year. CMS should also carefully monitor the extent to which beneficiaries are filing such appeals in order to determine whether future changes to the policy are needed.

11. Medicare Advantage and Part D Prescription Drug Program Quality Rating System

e. Contract Ratings

CMS notes that it is considering whether data should be collected, and measures scored, at the plan level rather than the contract level. CMS also notes it is exploring whether some measure data could be reported at a higher level (for example, a parent organization versus contract) in order to ease and simplify reporting while still providing useful information to beneficiaries.

ACS CAN supports CMS' proposal and urges CMS to require MA Organizations to include in its quality reporting as much product-level information as is practical. We agree with the information provided in the preamble that beneficiaries select a plan, rather than a contract. Providing information at the product level can skew quality results given that a specific plan's performance may differ from that offered by another plan within the same MA Organization.

We also agree with CMS that plan-specific information may not be practical for all quality measure data. The preamble notes the example of a call center, which would likely be operated by a parent organization, rather than at the plan level.

h. Adding, Updating, and Removing Measures

CMS notes that it will continue to review measure alignment with the private sector and may develop its own measures that are specific to the Medicare program. New measures would be proposed and finalized through the rulemaking process and would be on public display for at least two years prior to becoming a Star Ratings Measure.

ACS CAN is concerned that this proposal would lead to a lag between the time that measures are developed and approved to the time they are included in the Star Ratings program. We agree with CMS that public display and comment is an important component when determining whether to include a particular measure to the Star Ratings Program. However, we urge CMS to consider processes to ensure a more expedited approach to the inclusion of measures.

14. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (§§ 423.100, 423.120, and 423.128)

CMS proposes to allow Part D plan sponsors to remove, or change the preferred or tiered cost-sharing of, a branded product and replace the branded product with (or add to their formularies) therapeutically equivalent newly approved generic drugs. Under this proposal policy, Part D plan sponsors would not have to abide by the 60-day notification requirement when making this change. CMS also proposes changing other transition requirements from 60 days' notice to 30 days' notice.

ACS CAN urges CMS to reconsider its proposal. We support the use of generic drugs and encourage consumers to use these products because they often provide a lower-cost alternative for beneficiaries. However, we note that a beneficiary may not always be able to substitute a branded product for a generic equivalent. For example, a beneficiary may be taking multiple medications and switching one of those products may be antithetical to the overall treatment regimen. In addition, we are concerned that the changes in the notice requirement could create confusion for beneficiaries who are first informed of this change at the point of sale.

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

CMS requests comment on requiring Part D plan sponsors to include at least a minimum percentage of manufacturer rebates and all pharmacy price concessions received for a covered Part D drug in the drug's negotiated price at the point of sale. CMS does not propose any specific regulations at this time, but rather notes that feedback received through this request for information would be considered in future rulemaking.

ACS CAN is very concerned about the rising out-of-pocket costs for Medicare enrollees for their Part D medications, especially for prescribed drugs and biologics to treat cancer or other potentially serious or life-threatening conditions. These products are often placed on the non-preferred brand and specialty tiers of the Part D plan, with very high beneficiary coinsurance charges per prescription, based on the invoice price regardless of post-invoice discounts. Even when beneficiaries exceed the catastrophic threshold, they continue to pay cost sharing at five percent of the drug's invoice price. For those beneficiaries who do not qualify for full low-income subsidies, these out-of-pocket costs can be financially draining, sometimes leading them to take less than what they were prescribed or to fail to fill their prescriptions altogether. For beneficiaries being treated for cancer or other severe health conditions, skipping or halving dosages of their prescribed medications can have serious or even deadly consequences.

c. Manufacturer Rebates to the Point of Sale

CMS notes that it is soliciting comments on how to most effectively design a policy requiring Part D sponsors to pass through at the point of sale a share of the manufacturer rebates they receive.

ACS CAN greatly appreciates CMS' efforts to address the way in which Part D plan sponsors and their contracted Pharmacy Benefit Managers (PBMs) treat rebates that they receive from prescription drug manufacturers. We see value in the CMS' outlined approach to newly require the sponsors to pass through at least a minimum percentage of such rebates at the point of sale. It is the point-of-sale price that is used to calculate beneficiary cost-sharing.

As noted in the preamble, most Part D sponsors do not pass their savings resulting from prescription drug manufacturer rebates and price concessions to plan enrollees at the point of sale at the pharmacy. Instead, they have retained these price concessions (largely in the form of manufacturer rebates). Indeed, according to CMS, these amounts have increased nearly 24 percent per year which is nearly twice as fast as the growth in total Part D gross drug costs.[10] Although the retention of these rebates by plan sponsors may have helped those sponsors hold down their premiums below what experts anticipated, drug prices at the point of sale have not benefitted. For Part D enrollees, this has meant higher coinsurance and co-payment costs than if the rebates had been passed along at this point.

Moreover, because of the way in which the treatment of rebates interacts with the reporting of drug prices to Medicare, the drug prices posted on the *Medicare Plan Finder* (as reported by the Part D plan sponsors) have not always approximated the price actually encountered at the pharmacy. This means that enrollees (and potential enrollees) are less able to minimize both their costs and Medicare's costs by seeking and finding the Part D plan with the lowest-cost drug or the lowest-cost drug and pharmacy

[10] 82 Fed. Reg. at 56,419.

combination. As CMS also reports, its existing policy has resulted in trading off lower government costs for premiums with higher government costs paid in subsidies to cover the higher cost-sharing amounts for low-income subsidy enrollees as well as its higher reinsurance costs for all Part D enrollees in the catastrophic phase of the Part D benefit.

ACS CAN appreciates the tradeoff between higher premiums and lower cost-sharing for Part D enrollees that could result if CMS were to require Part D plan sponsors to reflect a percentage of the manufacturer rebates that they have received in the pharmacy price at the point of sale. Based on the analysis provided by CMS, the net effect on beneficiary costs would be to lower their costs. The amount of 10-year savings in reduced beneficiary costs could range from three percent to eight percent of their costs, depending on the percentage of all manufacture rebates that were required to be applied at the point of sale. The government's costs would rise modestly and manufacturer gap discounts would decrease.[11] Most importantly, CMS' outlined approach would lower the out-of-pocket burden for many beneficiaries, especially those who use drugs in highly competitive, highly rebated classes of drugs.

We share CMS' view that the outlined policy would have the added benefit of reducing the existing incentive for Part D plan sponsors to favor those drugs on their formularies for which there is a high price tag but for which the sponsors reap significant rebates over lower cost alternatives. It makes little sense to us that the Medicare program perpetuates a policy that has the effect of discouraging the use of lower-cost alternatives, when they exist, to the detriment of plan enrollees and to the Medicare program. Moreover, we agree with CMS that requiring the point of sale pass through of rebates would help to improve the transparency of Part D drug prices. On this note, we especially urge CMS to focus efforts on maximizing the accuracy of Part D plan prices that are reported by the sponsors for posting on the *Medicare Plan Finder*.

Finally, before moving to the next stage of CMS policy development, we urge CMS to provide more detailed analysis of the potential implications for beneficiaries and other stakeholders, incorporating a range of potential behavioral effects on manufacturers, plans and PBMs (effects on rebates, formulary placement and cost-sharing tiers, plan administrative costs), beneficiaries (premiums, cost-sharing, utilization), and Medicare (government) expenditures. Moreover, if CMS decides to propose a more limited application of the policy so that it would apply, for example, to a minimum percentage of rebates at the point of sale only for specific drugs or drug categories or classes that most directly contribute to increasing Part D drug costs in the catastrophic phase of coverage or drugs with high price-high rebate arrangements, the impact analysis should be tailored to that more limited application of the point of sale policy.

d. Pharmacy Price Concessions to Point of Sale

ACS CAN also supports the approach that CMS has outlined to require that all price concessions from pharmacies be reflected in the negotiated price that is made available at the point of sale and is reported to CMS, even when the price concessions are contingent upon the performance of the pharmacy.

As CMS describes, these price concessions that are obtained by the Part D sponsor or its Pharmacy Benefit Manager (PBM) currently do not benefit the beneficiary. In this context CMS notes that pharmacy price concessions, net of all pharmacy incentive payments, have grown faster than any other

[11] See, e.g., Table 10A. 82 Fed. Reg. at 56,425.

category of Direct and Indirect Remuneration (DIR) received by sponsors and PBMs. These concessions presently buy down a larger share of total Part D gross drug costs than ever before. Also, as with the manufacturer's rebate, these price concessions are instead retained by the sponsor or PBM and the beneficiary is charged higher cost sharing at the point of sale than they would be if the concessions were reflected in the point of sale price. Also, as in the case with manufacturer's rebates, price transparency is not achievable given the current manner in which these concessions are reported.

Based on CMS' ten-year impact analysis of its outlined approach for pharmacy price concessions at the point of sale (absent any modeling for potential behavioral effects), beneficiaries would experience savings both in terms of premiums and cost-sharing amounts. Net government costs would increase by a modest amount. We believe that this represents a reasonable tradeoff, especially in light of the improved medication adherence and patient well-being that can be expected as a result of reduced out-of-pocket cost.

Conclusion

On behalf of the American Cancer Society Cancer Action Network we thank you for the opportunity to comment on the proposed rule. 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