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March 7, 2014

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4159-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: CMS-4159-P – Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs
79 Fed. Reg. 1918 (Jan. 10, 2014)

Dear Administrator Tavenner:

The American Cancer Society Cancer Action Network (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. 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 appreciates the opportunity to comment on the proposed rule implementing changes to the Medicare Advantage and the Medicare Prescription Drug Benefit programs. ACS CAN supports many of the provisions outlined in the proposed rule. However, as discussed in detail below, we are greatly concerned with the proposed changes to the drug categories and classes of clinical concern (otherwise known as the "six protected classes") and urge CMS to reject this policy. We believe the proposed policy could negatively impact a cancer patient's overall health and wellbeing. With respect to CMS' proposed policy on improper prescribing practices, as discussed in greater detail below, we are concerned the proposed policy could have negative unintended consequences for cancer patients.

II. Provisions of the Proposed Regulations

A. Clarifying Various Program Participation Requirements

2. Two Year Limitation on Submitting a New Bid in an Area Where an MA Has Been Required to Terminate a Low Enrollment MA Plan (§ 422.504(a)(19))

CMS proposes to add a new contract requirement that Medicare Advantage Organizations are not permitted to submit a new bid of the same type of plan that has been non-renewed in the same service area as the non-renewed plan for two years after the non-renewal.

ACS CAN supports CMS' proposal. Medicare Advantage Organizations that have terminated their participation with the Medicare program because of low enrollment should be given appropriate time to examine what changes may be necessary to their product offering before they are permitted to launch a new product.

3. Authority To Impose Intermediate Sanctions and Civil Monetary Penalties (§ 422.752, § 423.752, § 422.760 and § 423.760)

CMS proposes to be able to impose intermediate sanctions on an organization that enrolls a beneficiary in a new plan or transfers a beneficiary to a new plan without prior consent. CMS also seeks to clarify that it would be a contract violation to violate the Part C and Part D marketing requirements. Finally, CMS proposes to clarify that either CMS or the Health and Human Services (HHS) Office of Inspector General (OIG) may impose civil monetary penalties.

ACS CAN supports CMS' proposed policies, which we believe provide appropriate safeguards for Medicare beneficiaries.

8. Timely Access to Mail Order Services (§ 423.120)

CMS proposes to add fulfillment requirements for mail order pharmacies and home delivery services offered by retail pharmacies. Specifically, CMS proposes to require mail order fulfillment within 5 business days (from receipt to date of shipment) for prescriptions requiring additional interventions (e.g., clarifying illegible orders, coordinating with multiple parties as part of drug utilization management) and 3 business days (from receipt to date of shipment) for prescriptions that do not require an intervention. CMS seeks comments on whether to establish additional requirements for beneficiary materials, such as clear definitions of processing time and delivery time; how to access customer support; how to submit a compliant via 1-800-MEDICARE; and beneficiary options for accessing medications when delivery is lost or delayed.

Overall, ACS CAN supports CMS' proposed changes. Beneficiaries who choose to take advantage of mail order have the ability to reduce out-of-pocket costs for prescription drugs they take for their chronic conditions. We believe the proposed 5-day and 3-day fulfillment requirements constitute reasonable timeframes by which plans must process and fill mail order prescriptions. Going forward, we urge CMS to monitor these timeframes to ensure that

beneficiaries have reasonable access to their medications. Plans are provided 5- and 3-days in which to process the prescription, but depending on mail services in some rare instances it may take the beneficiary up to 2 weeks to receive the prescriptions from the time the prescription was first mailed to the pharmacy to the actual delivery time. As part of its monitoring process, CMS should survey beneficiaries who use mail order services – particularly those who reside in rural areas – to determine whether beneficiaries are experiencing any delays in receiving their prescription drugs.

Moreover, we urge CMS to adopt additional protections to ensure beneficiaries have access to their medications. Part D plan sponsors should be required to clearly outline the expected process and delivery times and provide beneficiaries with a toll-free number so beneficiaries can decide whether mail order may be an appropriate option for their prescription drug needs. Part D plan sponsors also should have processes in place that will allow beneficiaries the option to obtain the prescription drug in cases where their drugs are lost or stolen. In such cases, we recommend that Part D plan sponsors be required to provide beneficiaries the option of expediting the delivery of the prescription drug and/or filling their prescription drug at a retail pharmacy (provided that the beneficiaries are assessed the same cost-sharing as they would had the prescription been filled through mail order).

9. Collections of Premiums and Cost Sharing (§ 423.294)

CMS proposes to require that once a Part D plan sponsor's bid has been approved by CMS, the Part D plan sponsor – either directly or indirectly through related party pharmacies – would be prohibited from waiving or reducing the collection of cost sharing and premiums for a specific enrollee.

While ACS CAN supports the general premise of CMS' proposal to prohibit waiving or reducing cost-sharing for a particular enrollee, we do not believe an outright ban on the practice is necessary. We believe that in some instances, plans should be allowed the flexibility to waive cost-sharing, particularly if the amount of the cost-sharing is of nominal value. In such instances, the administrative cost of collecting the cost-sharing may exceed the value of the amount collected. CMS may want to consider adding a safe-harbor whereby Part D plan sponsors would be permitted to waive or reduce a beneficiary's cost-sharing in instances where the cost sharing is a *de minimus* amount (e.g., equal to or less than $2).

14. Drug Categories or Classes of Clinical Concern and Exceptions (§ 423.120(b)(2)(v) and (vi))

CMS proposes considerable changes to the existing rules requiring Part D plans to cover all or substantially all prescription drugs within six drug categories and classes of clinical concern (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 the following categories and classes: anticonvulsants, antidepressants, antineoplastics, antipsychotics, antitretrovirals, and immunosuppressants. As discussed in more detail below, CMS proposes a new two-part test to

determine whether a category and class of drugs should be included in the protected classes. Based on this new test, CMS proposes to remove antidepressants and immunosuppressants from the list of protected classes beginning in calendar year (CY) 2015. Beginning CY 2016, CMS proposes to remove antipsychotics from the list of protected classes as well.

ACS CAN appreciates that CMS recognizes the need to protect beneficiaries' access to antineoplastics and continues to identify this class of drugs as a protected class. However, we are deeply concerned about the precedent being set by the proposed rule. Further, we are concerned that CMS' proposed policy could hinder beneficiaries' access to vitally important medications and negatively impact a cancer patient's overall health and wellbeing. For example, approximately one-quarter of cancer patients experience depression.[1] Individuals who suffer from depression must adhere to specific treatment regimes, and prescribers often try different medications until they find a prescription drug that best works for the individual beneficiary. We urge CMS not to adopt the proposed policy changes with respect to the six protected classes.

a. Categories of Classes of Critical Concern

In the preamble, CMS expressed concern that the current requirement that plans must cover all or substantially all of the prescription drugs within the six protected classes makes it challenging for Part D plan sponsors to negotiate lower prices for drugs within these categories and classes. CMS also expressed concern that the current six protected classes policy could result in overutilization given that plans are limited in their ability to impose utilization management tools (such as step therapy or prior authorization requirements). Rather, CMS proposed that drug categories and classes "should be subject to normal formulary and price competition unless we cannot ensure clinically appropriate access (and thus non-discriminatory benefit design) to our Medicare beneficiaries in any less anticompetitive way than requiring the inclusion on all Part D formularies of all drugs in that category or class." 79 Fed. Reg. at 1938. CMS then lists five protections – formulary transparency, formulary requirements, reassignment formulary coverage notices, transition supplies and notices, and the coverage and appeals process – that currently exist independent of the six protected classes requirement to ensure that beneficiaries have access to the drugs they need.

ACS CAN believes CMS' proposal is inconsistent with the purpose of the protected classes policy. In 2005, CMS created the six protected classes policy in order 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

[1] National Cancer Institute, Depression, available at http://www.cancer.gov/cancertopics/pdq/supportivecare/depression/HealthProfessional/page1, citing Henriksson MM, Isometsä ET, Hietanen PS, et al.: Mental disorders in cancer suicides. J Affect Disord 36 (1-2): 11-20, 1995.

risks and complications associated with an interruption of therapy for these vulnerable populations."[2] Severely curtailing a policy that was instituted to protect the most vulnerable beneficiaries seems an inappropriate response to concern that some plans have expressed regarding their ability to negotiate lower prices for drugs within the six protected classes.

b. Criteria Necessary to Identify Categories and Classes of Clinical Concern

CMS states that in light of the extensive beneficiary protections – particularly the coverage determination process and appeals process – clinical concern would arise only if access to drugs within a category or class for the typical individual who is initiating therapy must be obtained in less than 7 days. 79 Fed. Reg. at 1941. Thus, CMS proposes to modify the current six protected classes policy to require that Part D plan sponsors cover all drugs within a category or class that meets both of the following criteria:

- Hospitalization, persistent, or significant disability or incapacity, or death will likely result if initial administration (including self-administration) of a drug in the category or class does not occur within 7 days of the date the prescription for the drug was presented to the pharmacy to be filled; and
- More specific CMS formulary requirements will not suffice to meet the universe of clinical drug-and-disease-specific applications due to the diversity of disease or condition manifestations and associated specificity or variability of drug therapies necessary to treat such manifestations.

79 Fed. Reg. at 1942. In the preamble CMS defines a "typical beneficiary" as "for a given disease or condition, an individual who has the average clinical presentation of the relevant disease or condition." Id. at 1941.

ACS CAN has a number of concerns with CMS' proposal, as discussed below:

Typical beneficiary requirement: ACS CAN is concerned that CMS' proposed policy is limited to a "typical" Medicare beneficiary. In 2012, Medicare covered 50.7 million people, 8.5 million of whom had disabilities[3] approximately 24 percent of the total Medicare population were below age 65, and 22 percent were above age 85.[4] These individuals have very different and unique health care needs and it would be challenging to identify a "typical" beneficiary. A 65 year-old breast cancer patient's health care needs would be different from that of a 75 year-old with late stage pancreatic cancer. In addition, Medicare beneficiaries often have several co-morbid conditions that impact their treatment options; according to one CMS report, more than two-

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[2] Centers for Medicare & Medicaid Services, Medicare Prescription Drug Benefit Manual, Ch. 6 – Part D Drugs and Formulary Requirements, sect. 30.2.5, at 23.

[3] 2013 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds (May 31, 2013) available at http://downloads.cms.gov/files/TR2013.pdf.

[4] Medicare Payment Advisory Commission, A Date Book: Health Care Spending and the Medicare Program, June 2013.

thirds of Medicare beneficiaries had at least two or more chronic conditions.[5] Thus, CMS' proposed requirement to make a determination on the necessity of a protected class based on a "typical" beneficiary fails to take into account the diversity of the population.

In addition, the proposed rules fails to provide clarity on who makes the determination of what constitutes a "typical patient" and whether that determination will be made by CMS as part of the formulary review process, or whether individual plans will make that determination as part of their formulary development process. If individual plans are to make the determination, we are concerned that the policy will likely not be uniform across plan sponsors, and thus some plans' formularies may be more discriminatory than others. Even if CMS were to provide oversight, we question whether the timeframe under which the agency must approve plans' formulary requirements would provide adequate time to ensure beneficiary protection. This is of particular concern for plan year 2015, given that CMS will not likely have time to finalize this proposed rule in ample time to allow plans to develop their formularies.

Appeals process insufficient: CMS' proposed policy is predicated on the belief that beneficiaries have adequate notice and opportunity to utilize all other beneficiary protections provided under the Part D program. Unfortunately, in practice, this is often not the case. In its September 2013 meeting, the Medicare Payment Advisory Commission (MedPAC) discussed preliminary information on focus groups it conducted specifically around the issue of appeals and found that most beneficiaries are not made aware of their appeals rights and are unaware of how the appeals process works.[6] MedPAC also found provider frustration with the appeals process.

In addition, very little is known about the overall success of the Medicare appeals process. While Part D plan sponsors are required to report their appeals information to Medicare on a quarterly basis, this information is not made public. Researchers and other stakeholders are unable to independent verify whether the appeals process is working.

ACS CAN agrees that a functioning appeals process is one part of the checks and balances needed to ensure that beneficiaries are able to obtain their prescription drugs. However, there exists concern by a number of stakeholders that in practice the appeals process fails to provide the protections envisioned by CMS. Moreover, there has not been independent evidence the appeals process is working. Therefore, to assume that the current appeals system will provide beneficiaries with efficient and adequate recourse leaves beneficiaries particularly vulnerable. Without significant evidence that appeals are providing an effective safeguard, it is at best premature for CMS to suggest changes to the six protected classes policy. We urge CMS to

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[5] Centers for Medicare & Medicaid Services. Chronic Conditions Among Medicare Beneficiaries, Chartbook, 2012 Edition. Baltimore, MD. 2012, available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Downloads/2012Chartbook.pdf.

[6] Joan Sokolovsky, Shinobu Suzuki, and Lauren Metayer, Part D Exceptions and Appeals, Medicare Payment Advisory Commission Public Meeting (Sept. 12, 2013) available at http://www.medpac.gov/transcripts/part%20d%20exceptions%20&%20appeals.pdf.

postpone consideration of changes to the six protected classes policy until independent entities – such as the Government Accountability Office – have had an opportunity to conduct a formal evaluation of the current Medicare Part D appeals process.

c. Exceptions

The statue provides CMS with the authority to include exceptions to the requirement that Part D plans must cover all or substantially all drugs within the six protected classes. The rule proposes to retain the current exception that Part D plan sponsors are not required to cover drug products that are rated as being therapeutically equivalent (under the FDA's Orange Book); rather, plans only would have to cover one of these drugs. CMS also proposes to make an exception for utilization management edits (e.g., prior authorization requirements, step therapy) imposed for safety purposes.

In addition, CMS proposes a number of new exceptions: (1) drug products that are almost always covered under Part A or Part B; (2) compound products, unless the ingredients independently meet the definition of a Part D covered drug; (3) fixed combination dosage form drugs (other than antiretrovirals); and, (4) multi-source brands of the identical molecular structure and products that have the same active ingredient. CMS also proposes to allow Part D plan sponsors to impose prior authorization requirements for purposes of determining whether a drug is being used for a medically-accepted indication or to verify the drug is not covered under Part A or Part B. Finally, CMS is considering proposing a new requirement to allow Part D plans the ability to implement prior authorization requirements (including when used in connection with step therapy) to convert beneficiaries to preferred alternatives within the categories and classes of clinical concern for enrollees who are initiating the therapy (new starts).

While ACS CAN strongly opposes the proposed changes to the six protected classes policy, we believe that a few of the exceptions provided by CMS (e.g., an exception for drugs that are almost always covered under Part A or Part B) may warrant consideration if and only if CMS decides not to finalize its proposed change to the criteria for identifying categories and classes of clinical concern. However, it makes little sense to eliminate half of the six protected classes and at the same time allow Part D plan sponsors to make additional exceptions. Together, these policies could severely impact beneficiaries' access to needed medication.

Further, we have concerns with CMS' proposal to allow Part D plan sponsors to implement prior authorization requirements in the remaining protected classes. We do not believe that prior authorization or step therapy requirements are appropriate for categories and classes of drugs of clinical concern. CMS developed the six protected classes because the agency recognized that beneficiaries needed access to all the prescription drugs available within the category or class. The need for that kind of access has not changed. Allowing Part D plan sponsors to impose prior authorization or step therapy requirements for any beneficiary – regardless of whether they are a new enrollee to the plan – could negatively impact the health of the

beneficiary. Such policies could be particularly harmful to cancer patients, who need prompt access to antineoplastics in order to treat their cancer.

d. Analysis and Identification of the Categories or Classes of Clinical Concern

The preamble notes that CMS convened a consensus panel to determine which of the current six protected classes would meet the proposed criteria for the classes of clinical concern (e.g., significant health risk to the enrollee if the drug is not provided within 7 days and current beneficiary protections are inadequate). This panel determined that of the six protected classes, three categories (anticonvulsants, antineoplastics, and antiretrovirals) met both of the criteria, while three classes (antidepressants, antipsychotics, and immunosuppressants) did not. This panel also determined that while other categories and classes of drugs may meet one of the criteria of new two-part test, there were no new categories and classes of drugs that met both parts. CMS notes that while antipsychotics failed to meet both prongs of the test, at this time CMS will continue to require that Part D plan sponsors cover all drugs within this class.

ACS CAN urges CMS to release a more detailed report of the consensus panel's findings and allow interested stakeholders timely opportunity to review and comment on the panel's findings. While we appreciate that CMS released a brief synopsis of the panel's recommendations, the information provided is insufficient. For example, it is unknown how many individuals participated on the panel and whether any patients and/or consumer groups were represented (though based on the information made available, it appears as though the patient perspective was not represented in the panel's determinations). Moreover, it is unclear on what evidence the panel reached certain conclusions. CMS requires Part D plan sponsors to submit quarterly data on appeals but it is unclear whether this information was provided to inform the panel's deliberations.

15. Medication Therapy Management Program (MTMP) Under Part D (§ 423.153(d))

Initially CMS estimated that 25 percent of enrollees would qualify for Medication Therapy Management (MTM) services. However, participation has fallen far short of expectations. In 2011 fewer than 8 percent of beneficiaries were eligible to participate in the MTM program. CMS proposes a number of changes to the MTM program, which if adopted would increase the MTM eligibility rate to 55 percent, according to CMS estimates.

a. Multiple Chronic Disease

The Medicare Modernization Act (MMA) mandated Part D plan sponsors to create an MTM program targeted to beneficiaries who "have multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure)." § 1860D-4(c)(2)(A)(ii). CMS proposes to require that in order to be eligible to participate in a Part D plan sponsor's MTM program, a beneficiary must have at least one of the listed chronic diseases. In addition, CMS proposes to expand the list of chronic conditions to include cardiovascular disease,

diabetes, dyslipidemia, respiratory disease, bone disease – arthritis, mental health, Alzheimer's disease, and end-stage renal disease.

ACS CAN supports MTM programs, which provide Medicare beneficiaries with a coordinated examination of a beneficiary's prescription drug regimen and have been demonstrated to improve therapeutic outcomes for individuals enrolled in the program. ACS CAN urges CMS to consider expanding the list of targeted diseases to include cancer. The risk of being diagnosed with cancer increases with age – approximately 77 percent of all cancers are diagnosed in people aged 55 and older – and individuals' risk of developing cancer increases with age.[7] In addition, cancer can often be considered a chronic disease,[8] with some patients taking a course of treatment for many years, if not over the course of their lifetimes.

b. Multiple Part D Drugs

The MMA directed CMS to target certain beneficiaries (e.g., "targeted beneficiaries") to be included in a plan's MTM program. The statute defined targeted beneficiaries as Part D enrollees who are taking multiple Part D covered drugs. Under the proposed rule, Part D plan sponsors must target their MTM programs to beneficiaries who have two or more chronic conditions (discussed above) and who are taking two or more Part D covered drugs.

ACS CAN supports this provision. We believe that beneficiaries who have multiple chronic conditions for which they are taking multiple prescription drugs are more likely to benefit from an MTM program. The preamble to the proposed rule discusses whether plans should consider over-the-counter (OTC) or dietary supplements as drugs for purposes of meeting the "multiple drugs" test. While beneficiaries may use OTC and dietary supplements, it is unclear how Part D plans could target beneficiaries based on their utilization of these products because the plans would generally not have information on such utilization. Rather, we believe CMS struck the right balance in its proposal that MTM programs target individuals who are taking at least two Part D covered prescription drugs.

c. Annual Cost Threshold

The MMA did not provide a specific cost threshold under which enrollees would be eligible to participate in an MTM Program, and left CMS to determine the threshold amount on an annual basis. In the first year of the Part D program CMS set a cost threshold of $4,000. CMS has slightly altered this threshold over time and the 2013 cost threshold was $3,144. Given the prevalence of generic drug utilization, CMS proposes to lower the cost threshold to $620, which includes not only the cost of the prescription drug, but dispensing fees and sales tax. In addition, CMS proposes that Part D plan sponsors develop an effective strategy to ensure

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[7] See American Cancer Society, Cancer Facts & Figures 2014, available at http://www.cancer.org/acs/groups/content/@research/documents/document/acspc-041770.pdf.
[8] See Dianne C. Witter and John LeBas, Cancer as a Chronic Disease, OncoLog Apr. 2008, available at http://www2.mdanderson.org/depts/oncolog/pdfs-issues/08/oncolog4-08.pdf.

access to services for all enrollees who may be eligible for MTM services, including those who have disabilities and/or those who may have limited English proficiency.

ACS CAN supports CMS' proposal to reduce the cost threshold to $620. While beneficiaries with high prescription drug spending can certainly benefit from an MTM program, there has been some concern that the cost thresholds previously included in the Part D program were too high, thus preventing individuals who otherwise would benefit from the program from having access to it. In addition, ACS CAN encourages CMS to adopt proposals that would target specific populations, including beneficiaries who are enrolled in the low-income subsidy (LIS) program and those with limited English proficiency.

16. Business Continuity for MA Organizations and Part D Sponsors (§ 422.504(o) and § 423.505(p))

The preamble notes that in some cases of wide-spread power outages and natural disasters, a few MA and PDP plan sponsors (particularly those physically located in the impacted areas) failed to implement a continuity plan to continue plan operations and minimize disruptions to beneficiaries. CMS proposes to add a new contract provision that require Part D plan sponsors to develop and maintain business continuity plans that meet certain standards. These plans must be tested on an annual basis. Finally, CMS proposes that every Part D plan sponsor must restore essential functions no later than 24 hours after any of the plan sponsor's essential functions fail.

ACS CAN supports the proposed requirement. While few power outages and natural disasters are significant enough to impact the daily operations of a Part D plan sponsor, when these events do occur it is imperative that beneficiaries – particularly those with serious conditions like cancer - maintain access to Part D services.

Recognizing that simply having a plan can be insufficient, we support CMS' proposal that Part D plan sponsors be required to test their continuity plans on an annual basis. The proposed rule would require that Part D plans keep records of their continuity plans which would be made available to CMS upon request. We urge CMS to consider requiring Part D plan sponsors to file their continuity plans with CMS and notify CMS of the results of their annual continuity plan tests.

20. Limit Stand-Alone Prescription Drug Plan Sponsors to Offering No More Than Two Plans per PDP Region (§ 423.265)

CMS proposes to impose a maximum of two plans that each stand-alone PDP sponsor may offer in each PDP region. Specifically, CMS proposes to limit Part D plan sponsors to offering no more than one basic and one enhanced plan for a single PDP region. Because this proposed rule will be finalized as plan sponsors are preparing for the 2015 plan year, CMS proposes this new requirement would begin in 2016.

ACS CAN appreciates CMS' attempt to limit the number of plan offerings in each PDP region. While beneficiaries should have a choice of Part D plan options, too many options can hinder a beneficiary's ability to make an informed choice. At the same time, imposing an arbitrary limit on the number of plan offerings a Part D plan sponsor is permitted to offer in some cases could be detrimental to beneficiaries. As part of the final rule, we urge CMS to require Part D plan sponsors to offer meaningful differences between their plan offerings. Such differences should be made readily apparent to beneficiaries so that beneficiaries who search for plans on the Medicare plan finder should be easily able to ascertain which plan may best suit their needs.

22. Applicable Cost-Sharing for Transition Supplies: Transition Process Under Part D (§ 423.1230(b)(3))

Current Part D regulations fail to address the cost sharing that should apply when Part D plans provide a temporary fill in cases where an enrollee requests a fill of a non-formulary drug during her transition time period. CMS proposes to clarify that when providing a transition supply to an enrollee, the Part D plan sponsor must charge cost-sharing for a temporary supply. For low-income subsidy (LIS) individuals, the Part D plan sponsor would be prohibited from charging higher cost sharing for the transition supplies than the statutory maximum copayment amount. For non-LIS enrollees, the sponsor must charge the same cost-sharing for the transition supply as would be charged if the drug were approved through the formulary exceptions process; for formulary drugs subject to utilization management edits, the plan sponsor must charge the same cost-sharing as would apply if the utilization management criteria were met.

ACS CAN supports CMS' proposal. Individuals with cancer often must adhere to specific treatment regimens and the proposed regulations provide an appropriate transition process while the beneficiary seeks an appeal or works with her provider to find an appropriate alternative. We appreciate CMS' attempt to ensure consistency across plans as beneficiaries work through their transition process.

29. Any Willing Provider Pharmacy Standard Terms & Conditions (§ 423.120(a)(8))

CMS previously has allowed plans to have separate terms and conditions contracts for their preferred and non-preferred pharmacies. In the proposed rule, CMS proposes to require that Part D Plan sponsors create three standard rates, terms and conditions to be offered to any willing pharmacies: (1) a standard monthly rate; (2) a preferred monthly rate; and (3) an extended days' supply rate. In addition, CMS proposes to require that any preferred rates must reduce both beneficiary cost sharing and the cost of the prescription drugs to the Part D plan sponsor.

ACS CAN supports CMS' proposed any willing pharmacy policies. In addition, we urge CMS to require plans to clearly identify to the beneficiary which pharmacies are preferred and which are non-preferred. As part of this transparency, beneficiaries should be given clear information on how their cost-sharing differs depending on whether they use a preferred, non-preferred or

mail order pharmacy. This information should be provided to both current plan enrollees and prospective plan enrollees.

We urge CMS to ensure that network adequacy standards extend to preferred pharmacies and not just to the Part D plan sponsors' overall pharmacy network. Currently some beneficiaries – particularly those in rural and frontier areas – may not have access to a preferred pharmacy. At the very least, these beneficiaries should be given advance notice of the preferred pharmacy locations to determine whether they would be a convenient option.

Finally, we support CMS' proposed requirements that Part D plan sponsors must secure lower drug prices at preferred pharmacies to ensure the use of preferred pharmacies does not lead to increased costs for the beneficiary or the Part D program.

30. Enrollment Requirements for the Prescribers of Part D Covered Drugs (§ 423.120(c)(5) and (6))

Beginning January 1, 2015, CMS would require that qualified prescribers of covered Part D drugs have an approved enrollment record in the Medicare program or have a valid opt-out affidavit on file with the Medicare program. Currently, Medicare requires prescribers to have an individual National Provider Identifier (NPI), but CMS notes that this is not a practitioner credentialing system. Rather, the Medicare fee-for-service enrollment process validates each enrollment application. CMS proposes to require Part D plans to deny a pharmacy claim if the claim does not have a valid NPI and the physician (or eligible prescriber) is not enrolled in the Medicare program (or have a valid opt-out).

ACS CAN supports CMS' proposal, which we believe will be useful tool in combating fraud in the Medicare program. However, we encourage CMS to conduct extensive outreach to prescribers to ensure that those who have not already enrolled in Medicare have been provided adequate opportunity to do so in advance of the implementation of this policy. In addition, CMS may want to consider creating a temporary transition period to ensure that beneficiaries continue to have access to their prescription drugs. In implementing the final rule, we urge CMS to clarify whether Part D plan sponsors would be able to accept a pharmacy claim for an automatically generated refill prescription if the prescriber were not enrolled in the Medicare program. In order to avoid potential access problems at the beginning of the year, ACS CAN encourages CMS to consider implementing this policy on only new prescriptions.

31. Improper Prescribing Practices (§ 424.535)

CMS proposes to combat improper Part D prescribing in two ways. The first is to require prescribers to be in good standing with their state licensing board as well as be registered with the DEA in order to enroll or remain enrolled as a Medicare provider. The second measure is a proposal for CMS to have independent authority to evaluate prescriber practices and remove a prescriber from the Medicare program that is deemed to be "abusive" and a "threat to the health and safety of Medicare beneficiaries."

While the stated goal of reducing abusive prescribing practices is laudable and ACS CAN supports the requirement for prescribers to be DEA and state licensed, the creation of independent CMS enforcement power to remove providers who are "abusive" and a "threat to the health and safety of Medicare beneficiaries" is a significant change that could have unintended consequences for cancer patients if not implemented with care. Specifically, we are concerned by the lack of a definition of "abusive" and a "threat to the health and safety of Medicare beneficiaries." While CMS' desire for flexibility is understandable, this ambiguousness could lead to very uneven enforcement and have a chilling effect on the practice of oncology as noted below. Enforcement must be calibrated such that only true outliers are captured, and the majority of practitioners who are following accepted medical practice do not feel intimidated with the threat of enforcement such that they ration otherwise normal care from their patients.

Cancer patients are frequently treated with off-label drugs and experience high levels of pain that require analgesics, two prescribing areas that CMS has identified for enhanced scrutiny. Off-label use of drugs in oncology is in many cases scientifically supported and considered the standard of care. Off-label drug use represents anywhere from 30 to 75 percent of all prescriptions in oncology[9] and especially is employed in cases of rare cancers (including pediatric cancers), cancers where no effective treatments exist, and for palliative purposes. Further, cancer-related pain is reported by up to two-thirds of cancer patients, and much of this pain can be alleviated by opioid analgesics,[10] while pain more broadly has been identified by the Institute of Medicine as a public health priority.[11] The proposed rule's focus on evaluating general appropriateness of prescribing practices as well as the specific emphasis on controlled substances could very easily target oncologists and palliative care specialists whose prescribing practices may be outside of the norm when compared to a broad range of providers, but could be well within justified practice given the patients and diseases with whom they specialize. Fear of CMS sanction could discourage providers from properly managing pain and treating cancer patients with the most up-to-date therapeutic protocols and lead to drug substitutions with untoward effects.

In the preamble, CMS noted the effect that the 2013 implementation of the Part D Overutilization Monitoring System (OMS) had on opioid prescribing. These data indicate that

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[9] See Soares M *(2005) "Off-label indications for oncology drug use and drug compendia: History and current status." J Oncol Pract; 1:102–105;* Conti RM, Bernstein AC, Villaflor VM, et al. (2013) "*Prevalence of Off-Label Use and Spending in 2010 Among Patent-Protected Chemotherapies in a Population-Based Cohort of Medical Oncologists" JCO* epub ahead of print.

[10] See Brawley OW, Smith DE, Kirch RA (2009) "*Taking Action to Ease Suffering: Advancing Cancer Pain Control as a Health Care Priority" CA Cancer J Clin*; 59:285-289; Van den Beuken-van Everdingen MH, de Rijke JM, Kessels AG, et al. (2007) "*Prevalence of pain in patients with cancer: a systematic review of the past 40 years"* Ann Oncol 18: 1437-1449 2007.

[11] Institute of Medicine, *"Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research,"* Washington, DC: The National Academies Press (June 2011).

the proportion of the population suspected of improper opioid use is less than one-tenth of one percent of overall Medicare Part D enrollees, and the implementation of OMS reduced this figure by six-hundredths of a percentage point (10,000 cases) despite only referring 13 cases for enforcement. Over the same time period, the overall proportion of beneficiaries obtaining opioid prescriptions dropped by three percent, which would translate into several hundred thousand fewer patients provided with opioids when compared to historical levels. It is not possible determine from these data to what extent patients with valid needs were denied access because of restrictive policies, but the data suggest that restrictive policies have the potential to reduce non-questionable prescribing to a much greater extent than questionable prescribing. It is critical that CMS balance efforts to curb improper prescribing with its obligation to provide necessary medical care, such that barriers are not erected for patients with valid medical needs.

With respect to proposed CMS power to remove a prescriber who is abusive and represents a threat to the health and safety of Medicare beneficiaries, we have the following comments on a few of the proposed factors under consideration by CMS:

- *Whether there are diagnoses to support the indications for which the drugs were prescribed;*

Standard Part D Event (PDE) data collection does not include diagnosis codes to accompany a prescription. How does CMS intend to cross-reference Part D prescriptions with appropriate diagnoses? In many cases, administrative claims data may not provide sufficient detail to make appropriateness determinations. Further, Medicare supports the payment of any medication not only with an FDA label for a given diagnosis, but also for drugs listed in compendia per 1860D-2(e)(4) as being appropriate for a given diagnosis. In determining appropriate prescribing for cancer drugs, CMS must include all scientifically supported indications whether on the FDA label or not.

- *Whether there are instances where the necessary evaluation of the patient for whom the drug was prescribed could not have occurred (for example, the patient was deceased or out of state at the time of the alleged office visit);*

The implementation of this provision needs to be calibrated to catch true outliers, such as those who are deceased, and should not be applied in such a strict manner as to flag beneficiaries who may be evaluated outside their normal residence (e.g., those seeking specialized treatment at out-of-state facilities, those who spend extended periods staying with children, those with multiple homes, professionals who travel frequently for work, etc.). A focus on the prescriber's status (deceased, out of the country, etc.) would be more efficient than attempting to determine travel patterns of individual beneficiaries.

- *Whether the physician or eligible professional has prescribed controlled substances in excessive dosages that are linked to patient overdoses;*

It should be noted that patients with chronic pain often develop tolerance to pain medication, requiring dose escalation. In addition to absolute dosage, CMS should look at patterns of prescriptions, for example a provider who is treating large numbers of pain patients would likely have patients receiving a spectrum of dosages from low to extremely high, indicative of the varying needs and tolerance levels of the patients. A prescriber whose patients are all on high dosages is much more concerning than a prescriber who has a subset of high-dosage patients.

- *Whether certain criteria should be given more or less weight than others.*

ACS CAN believes that CMS should exercise caution in basing program removal on any individual criterion. As noted above, many providers involved in treating cancer patients frequently prescribe drugs off label and prescribe pain medications in quantities that may justifiably fall outside the norm when compared to other specialties. Failure to meet one criterion may serve as a "red flag" to suggest further investigation, but the totality of information should be considered to determine truly abusive behavior. While the proposed rule does not explicitly mention appeal rights, it will also be important for practitioners to have a fair forum to defend their actions should they be accused by CMS of wrongdoing.

32. Transfer of TrOOP Between PDP Sponsors Due to Enrollment Changes during the Coverage Year (§ 423.464)

CMS proposes to codify the requirement regarding True Out-Of-Pocket (TrOOP) balance transfers when a beneficiary changes plans mid-year. CMS will require that Part D plan sponsors must report to CMS a beneficiary's TrOOP data in real time and apply the costs promptly.

ACS CAN supports CMS' proposal. In cases where a beneficiary switches a plan, the plan should be required to transfer a beneficiary's TrOOP balance as soon as possible so that the beneficiary experiences a seamless transition between plans.

C. Strengthening Beneficiary Protections

2. MA-PD Coordination Requirements for Drugs Covered Under Parts A, B, and D (§ 422.112)

Citing concern that some MA-PDs fail to adopt uniform policies to expeditiously determine whether a prescription drug is covered under Medicare Part A, Part B, or Part D, CMS proposes to refine its current policies. CMS proposes that plans establish appropriate messaging and processing requirements with Part D network pharmacies to ensure that in cases where a drug is denied under Part D because the drug is covered under Part A or Part B, the Part A/B coverage is authorized or provided to the enrollee "as expeditiously as the enrollee's health

condition requires." 79 Fed. Reg. at 2009. MA-PDs would be required to have a system in place to "accurately and timely adjudicate claims" at the point of service (POS). Id. In addition, CMS is considering requiring MA-PD plans to coordinate benefits and authorize coverage of all Part A, Part B, and Part D medications at the POS.

ACS CAN supports this proposed policy, which we believe will help better inform beneficiaries of their ability to access medically necessary prescription drugs. Often beneficiaries may be denied Medicare Part D coverage for their prescription drugs and may not be adequately informed that the product is available for coverage under Medicare Part A or Part B.

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,

Kirsten Sloan
Senior Policy Director
American Cancer Society Cancer Action Network