



JAMES L. MADARA, MD  
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org  
t (312) 464-5000

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Andrew Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building, Room 445-G  
200 Independence Avenue, SW  
Washington, DC 20201

**Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2016 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2016 Call Letter**

Dear Acting Administrator Slavitt:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to offer comments to the Centers for Medicare & Medicaid Services (CMS) regarding the 2016 Advance Notice for Medicare Advantage (MA) and Medicare Part D. The AMA also appreciates that CMS has responded positively to a number of our prior suggestions.

**Network Adequacy**

The AMA welcomes and strongly supports the CMS proposal to fortify its network adequacy standards for MA plans. We are pleased that CMS has clarified to MA plans that physicians whose practices are closed or who are otherwise unavailable cannot be used to successfully meet MA network adequacy standards, and that CMS is addressing a range of issues with online provider directories. Clearly, directories should not include physicians who are no longer contracting with the MA plan because they have retired from practice, moved, or died. We agree that network directories should also clarify when physicians who are still in the MA plan's network are not accepting new patients.

The AMA urges CMS to finalize its additional guidance that MA plans must establish and maintain proactive, structured communications with their network physicians in order to assess their true availability on a timely basis and comply with applicable network access requirements. We applaud the requirement that plans must implement protocols to effectively address inquiries and complaints about patients being denied access to contracted physicians, and that they must provide real-time updates to their online directories.

In addition to the information that CMS plans to require plans to collect on office addresses, phone numbers, and hours, the AMA recommends that plans be compelled to maintain up-to-date information on the specialty and/or subspecialty of each physician in the network, as well as whether they practice on

a full-time basis or part-time. For example, over time a pulmonologist may become a sleep medicine specialist and the network directories should reflect these types of changes. In addition, even if a physician's office is open full-time, that does not mean that all physicians in the group are practicing full-time.

The AMA also supports CMS' plans to monitor compliance with these regulations, including engaging an additional contractor to verify the accuracy of online provider directories; developing a new audit protocol; and indicating to plans that failure to maintain complete and accurate directories, as well as failure to have a sufficient number of physician practices open and accepting new patients, may subject the MA plans to civil monetary penalties or enrollment sanctions. In addition, CMS states that it is considering requiring plans to provide and update network information in a standardized, electronic format for eventual inclusion in a nationwide provider database. The AMA agrees that such an approach could be leveraged by application developers to create user-friendly search applications that will be more accessible, up-to-date, and useful than the current, non-standardized websites or printed directories. These applications could allow patients to make more informed decisions about their health care coverage because they would know whether or not their physicians are in the plan before they enroll, and, if their physicians are not in the plan, they could see which plans their physicians do accept.

The AMA urges CMS to proceed with and finalize its network adequacy and directory accuracy proposals.

#### **Part D Annual Notice of Change (ANOC)**

Currently, each Medicare Part D plan is required to provide an ANOC to each enrolled beneficiary in the fall. The sample ANOC is more than 80 pages in length and provides general information to patients on cost sharing for each tier of coverage in the subsequent year. Annual formulary changes and additions to Part D plans' drug utilization management (DUM) rules (from added quantity limits, step therapy, and prior authorization requirements) are extremely confusing to patients and may interfere significantly with medication adherence. They also represent a major administrative burden for physician practices.

Separately from the ANOC, Part D plans send each enrolled patient a monthly statement listing their filled prescriptions, with details on how much the plan paid for each prescription, as well as the patient's cost-sharing. The AMA recommends that these monthly statements be used as the model for the ANOC. There is no reason that a plan must send a generic ANOC to each enrollee when detailed patient-specific information is readily available. The ANOC would be a much more useful tool if it showed the specific changes in the plan that would affect the specific patient receiving the form. For example, if a patient received a prescription for a drug in Tier 2 during one year, and that drug is being moved to Tier 3 for the subsequent year, the ANOC should provide that specific information to the patient. General information about formulary changes is simply not sufficient. Providing this information in the fall as part of the ANOC would also allow patients to discuss formulary and DUM changes with their physicians much sooner, potentially avoiding the need for transition fills and expedited exception requests.

#### **Part D Straddle Claims: Method for Calculating Beneficiary Share of Negotiated Price**

The AMA urges CMS to examine how Medicare Part D and Medicare Advantage-Prescription Drug Plan (MA-PD) sponsors are applying the straddle drug pricing rules and to direct sponsors to utilize a method that ensures that beneficiaries receive the maximum protection from unfair cost shifting.

Under Medicare Part D, each time a beneficiary purchases a prescription drug, the beneficiary is responsible for paying either a fixed-dollar amount (copayment) or a percentage of the cost (coinsurance). The amount of the beneficiary's payment depends on which of four coverage phases the beneficiary is in. The Medicare prescription drug plan coverage phases generally include the following:

- *Initial Deductible* phase where the beneficiary is responsible for 100 percent of the prescription drug purchase cost (though not all Medicare Part D plans include a deductible).
- *Initial Coverage* phase where the beneficiary shares the negotiated retail cost of the prescription purchase with the Part D plan, either as a coinsurance percentage or as a fixed copayment.
- *Coverage Gap* phase (which is often referred to as the donut hole) where the beneficiary is 100 percent responsible for the purchase price of the prescription drug minus a percentage discount (though it is important to note that certain Part D plans do offer some coverage in this "gap").
- *Catastrophic Coverage* phase where beneficiaries, after spending a certain amount on their prescription drugs, are to pay a maximum of five percent of the negotiated retail drug prices.

The Affordable Care Act (ACA) altered the above framework so that current beneficiaries in the Coverage Gap phase will pay less than 100 percent of their costs. It closes the Coverage Gap phase altogether as of 2020, so that enrollees will pay 25 percent of their costs (or the actuarial equivalent of an average expected payment of 25 percent) until they enter the Catastrophic Coverage phase. This will be achieved by offering percentage discounts that are gradually increased for brand name and generic drugs in the Coverage Gap.

The AMA is aware that Medicare Part D prescription drug plan benefit designs vary considerably and may or may not include an initial deductible, and may include some coverage in the Coverage Gap phase (beyond the ACA statutorily mandated discounts to close the Coverage Gap). Part D prescription drug plans must have a "standard benefit" package or an actuarially equivalent benefit design. Part D plan sponsors may also offer "enhanced" plans that provide benefits in addition to the standard benefit which typically includes some coverage during the Coverage Gap phase. Therefore, calculating a beneficiary's share of the negotiated purchase price will vary depending on the benefit design of the Part D plan.

**What Are Straddle Claims?** Straddle claims are prescription drug claims that cross phases of a beneficiary's Medicare Part D prescription drug plan benefit. Generally, a straddle claim usually occurs in three instances when the cost of the prescription drug purchase crosses the following phases:

- From the Initial Deductible phase into the Initial Coverage phase where coinsurance or copayment applies.
- From the Initial Coverage phase where copayment or coinsurance applies into the Coverage Gap phase where discounts apply (and where some plans offer coverage).
- From the Coverage Gap phase into the Catastrophic Coverage phase where copayment or coinsurance may apply, but only up to a maximum of five percent of the negotiated retail price.

The following example shows how a beneficiary's share of the negotiated price could be calculated when a claim straddles the Initial Deductible and Initial Coverage phases. Mr. Smith, a Medicare beneficiary, is enrolled in a Medicare Part D plan with an initial deductible of \$250. Mr. Smith's cumulative covered retail drug purchases to-date equal \$200 and now Mr. Smith just purchased a covered prescription drug with a negotiated retail price of \$100.

- Of the \$100 purchase, \$50 is under the \$250 Initial Deductible limit. Mr. Smith is responsible for 100 percent of this \$50 of prescription costs.
- The remaining \$50 is a claim that moves Mr. Smith into the Initial Coverage phase. Mr. Smith's Part D plan includes a 25 percent coinsurance (or \$12.50) and his Medicare Part D prescription drug plan pays 75 percent.
- Therefore, Mr. Smith pays \$50 (from the Initial Deductible phase) plus \$12.50 (from the Initial Coverage phase) for a total of \$62.50.
- Mr. Smith is not responsible for the full negotiated retail price of \$100.

CMS Policy: The “Copay-First” Approach. CMS has not enforced a consistent method to determine a beneficiary’s portion of the negotiated price when a claim straddles the Initial Coverage phase and the Coverage Gap phase. At least three methods have been identified and CMS has permitted Part D plans to use the approach that is the least favorable to beneficiaries, dubbed the “Copay-First” approach. In August 2014, a Federal District Court in Stanley H. Epstein v. U.S. Department of Health & Human Services (HHS) dismissed a beneficiary lawsuit brought against HHS to challenge the "Copay-First" approach" for handling Medicare Part D claims that straddle the gap between the Initial Coverage phase and the Coverage Gap phase. The Copay-First approach allows health plans to resolve straddle claims by counting a beneficiary’s copay toward the initial coverage limit before determining the Part D plan’s share of the prescription drug negotiated retail rate.

In 2010 the plaintiff, Mr. Epstein, was enrolled in a Part D plan and he purchased a covered prescription drug called Actonel. Reportedly, at the time of this purchase, he had incurred \$2,746.67 in prescription drug costs and he was \$83.33 below his plan’s Initial Coverage phase limit. Because the Actonel cost \$334.92, his purchase pushed him into the Coverage Gap phase.

During the Initial Coverage phase, Epstein’s copayment for the Actonel was \$187.50. If his entire Actonel purchase had been made during the Initial Coverage phase, the Part D plan’s share of the costs would have been \$147.42 (i.e.  $\$334.92 - \$187.50 = \$147.42$ ). There are three possible approaches to calculate Mr. Epstein’s cost of the straddle claim in the above scenario, including:

- Initial Coverage phase approach - The Part D plan should pay the \$147.42 share for Mr. Epstein’s straddle claim because he was still in the Initial Coverage phase when he made the purchase.
- Pro Rata approach - The Part D plan must at least pay its pro rata share of all costs beneath the initial coverage limit. Under this approach, the Part D plan would pay its 44 percent share of the \$83.33 he paid for the Actonel, \$36.66, before he reached the \$2,830 initial coverage limit.
- Copay-First approach - Because Mr. Epstein’s \$187.50 copay for the Actonel pushes him into the Coverage Gap phase, the Part D plan concluded that Mr. Epstein was not entitled to any benefits. The Part D plan had counted Mr. Epstein’s copay towards the initial coverage limit before determining its share of the cost. This is the “Copay-First approach” to straddle claims.

The Copay-First approach results in beneficiaries paying more out-of-pocket, when there are at least two alternative methods for calculating respective costs that are more equitable. The AMA strongly urges CMS to direct Part D and MA-PD sponsors to utilize the Initial Coverage phase approach when calculating the beneficiary’s share of costs for straddling claims and to evaluate other practices—including tier copayments and straddle claims—to assess whether beneficiaries are subject to unfair cost-sharing.

## Opioid Overutilization Management

The draft Call Letter provides data demonstrating that the Part D overutilization policy has played a key role in reducing opioid overutilization in the program in just nine months. In the fourth quarter of 2013, 13,393 new cases of potential opioid overutilization were identified and, in the third quarter of 2014, this figure dropped to 9,002.

Instead of sticking with its current successful approach, however, for 2016 CMS proposes to have Part D plans implement point-of-sale edits tied to cumulative daily morphine equivalent doses (MED) of opioid analgesics. As we have stated in previous comment letters, the AMA strongly opposes this new approach. Patients with cancer and other conditions that can cause severe pain, for example, may be prescribed a rescue dose for flare-ups that would cause them to exceed the Part D MED limits. An additional drug in the opioid class also may be prescribed because of an adverse reaction to a previously prescribed drug, or due to increased tolerance and corresponding need for opioid rotation. A conversation with the patient's prescriber or a prior authorization requirement for doses above a certain MED would allow the plan to learn whether or not the dose was appropriate for the patient. In the absence of an accepted standard, however, point-of-sale edits tied to MED would essentially be arbitrary and could leave medically fragile patients without access to critically important medications.

For these same reasons, the AMA also opposes setting a performance standard for plans based on measuring the "Opioid Daily Dose rate" as the number of opioid days greater than 120 milligrams (mg) MED/1000 opioid utilization days. There is no basis to conclude that 120 mg MED is a generally recognized standard signaling opioid misuse. It is further puzzling that when looking at utilization of short-acting opioid analgesics, CMS proposes an even lower standard of 90 mg cumulative MED for greater than 90 days. Research on opioids has found that it does not matter in terms of overall clinical benefit whether patients are treated with short-acting or long-acting opioids.

We also question the plan to measure "high-dose opioids in opioid naïve patients." While clinical guidance supports careful introduction of opioid use in patients who have not previously been on these drugs, it is not appropriate for Part D plans to substitute their judgment for that of the patient's treating physician, nor do the plans have any information available to make such judgments. Part D plan sponsors essentially have the information that is included on a patient's prescription. However, they do not have access to the type or level of information that is crucial to support a conclusion that a patient is opioid naïve or that their prescribed dose is too high, such as the patient's individual treatment plan, diagnosis, medical history, and laboratory and other test results. The AMA agrees that measures of "concurrent buprenorphine and opioid use for more than 90 consecutive days" and "concurrent opioid and other CNS depressant use from multiple prescribers" could be useful signals of potentially unsafe practices.

## Advance Beneficiary Notices

In a May 5, 2014, memorandum to MA plans, CMS addressed the plans' improper use of advance notices of non-coverage, which are known in the standard Medicare program as "Advance Beneficiary Notices" or ABNs. The memo explains that MA plans are required to have in place a process for making determinations about whether a service will be covered, and that they are to use a "Notice of Denial of Medical Coverage" form to inform patients if their coverage request is denied, explain the reason for the denial, and tell them their appeal rights. The draft Call Letter also addresses this issue and indicates that CMS plans to revise its Part C standardized denial notice to provide clearer information about coverage and payment denials and the information needed to produce a favorable coverage decision.

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As CMS considers these improvements to the process, the AMA recommends that a standard form be developed that can be used with all MA plans and also with patients in the standard Medicare program. The issues are the same and in all cases involve questions about whether Medicare or the patient's MA plan will cover a service. Physicians need to have a standard way of informing patients if:

- (1) There is a question about whether the service will be covered;
- (2) How this question can be resolved by either the MA plan or Medicare;
- (3) What the patient's appeal rights are in the event of a non-coverage decision; and
- (4) Options for the patient to obtain the service if it is not covered, such as paying the physician's fee out-of-pocket or not getting the service.

The AMA agrees that MA plans need to do a better job of explaining their coverage policies and the rationale for denials, as well as informing patients of their appeal rights. CMS also needs to consider the physician's role, however. The Call Letter discusses situations when the MA plan may need to contact the service provider to get more information, but fails to acknowledge or address the fact that physicians also play a vital role in communicating with patients about their diagnosis and treatment options. Physicians need to have a form that they can provide to MA patients, just as they do in the standard Medicare program, which explains what to do if there are questions about whether a particular service will be covered or not. To simplify and reduce administration burdens, the best solution would be a standard procedure that could be used with all Medicare beneficiaries whether they are in standard Medicare or in MA.

### **Chronic Care Management**

In 2015, Medicare began providing separate payment for chronic care management services under the Medicare Physician Fee Schedule for CPT code 99410. The agency has been working to educate the physician community about this newly billable service. The AMA recommends that CMS also inform MA plans about this new service and ensure that the plans are providing appropriate coverage when chronic care management services that meet the criteria for Medicare payment are provided to their enrollees. A recent educational program on the new code offered by CMS staff noted that the service cannot be billed for patients in an advanced primary care practice demonstration and can be billed for patients assigned to an accountable care organization, but did not address provision of the service for enrollees in MA plans.

We appreciate this opportunity to share the views of the AMA regarding the MA and Part D programs and thank you for considering our comments.

Sincerely,

James L. Madara, MD