Obama Administration Issues Final 2010 Call Letter for Medicare Advantage Organizations

Written by Thomas Barker, Maia M. Larsson

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On March 30, 2009, the Centers for Medicare & Medicaid Services (CMS) issued its 2010 Call Letter for Medicare Advantage (MA) organizations (MAOs) and Part D plans. The purpose of the annual Call Letter is to provide information that will help Medicare Advantage organizations, contractors, and prescription drug plan (PDP) sponsors prepare their bids for the upcoming contract year. Bids are due in to CMS on June 1, 2009.

Prior to the issuance of this final Call Letter, the Bush Administration had issued a 2010 Draft Call Letter on January 9, 2009. The Obama Administration rescinded this draft Call Letter on January 22, 2009 to consider the issues further, and reissued a revised 2010 draft Call Letter on February 23, 2009. The final Call Letter issued on March 30 shows the imprint of the new Administration as it makes changes to the MA program that show a focus on greater transparency, ease-of-use for beneficiaries, and simplification of the Medicare Advantage program.

The following are examples of the different approach the 2010 Call Letter takes toward private Medicare Advantage plans:

- Urging the elimination of Medicare Advantage plans with little or no enrollment or duplicative plan offerings and reviewing the operation of plans with low enrollment (or less than 10 enrollees) for more than three years.
- Announcing the consideration of rule making that would limit the number of plans in a certain area to no more than a specified number of benefit designs.
- Giving plans that have an out-of-pocket maximum deductible amount that is over $3,400 "greater scrutiny of cost sharing" in determining whether the plans are discriminatory; giving plans with no maximum out-of-pocket level the greatest scrutiny; and considering amending the regulations to impose a requirement for an out-of-pocket maximum amount.

In addition, the 2010 Call Letter addresses the following five key items which are of particular significance to Medicare Advantage Organizations and Part D plans. These key items are (1) protected classes of drugs, (2) prohibition on the use of "fail-first" policies on "off-label" indications of covered Part D drugs, (3) medical loss ratio disclosure, (4) private fee-for-service plans, and (5) payment policies including coding adjustment and growth percentage.

Formulary Design and Protected Classes of Drugs

The 2010 Call Letter states that there will be "no change in our six classes of clinical concern policy outlined in section 30.2.5 of Chapter 6 of the Prescription Drug Benefit Manual." 2010 Call Letter, p. 58. There are currently six "protected classes" in the Medicare Part D benefit, which are intended to protect vulnerable populations, and include: Antidepressant, Antipsychotic, Anticonvulsant, Immunosuppressant (to prevent rejection of organ transplants), Antiretroviral (for the treatment of infection by retroviruses, primarily HIV), and Antineoplastic (only those chemotherapy drugs that are generally not covered under Medicare Part B). These six protected classes were created in response to a provision in section 1860D-11(e) of the Social Security Act, which states that prescription drug plans (and their formulary and tiered formulary structure) may not be designed in such a way that discourages enrollment by certain part D eligible individuals. In 2005, CMS directed Part D formularies to include all or substantially all drugs in the six protected classes mentioned above.

Section 176 of the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 (Pub. L. No. 110-275, 122 Stat. 2494, 2581 —

82) was intended to codify the CMS "six protected classes" policy. Under MIPPA, Part D formularies are generally required to cover all covered Part D drugs that meet two criteria: (1) restricted access to multiple drugs would have major or life threatening clinical consequences for individuals who have a disease or disorder treated by the drugs, and (2) there is significant clinical need for individuals who have a disease or disorder to have access to multiple drugs within a category. CMS has discretion to create exceptions to the requirement. In an interim final rule released January 15, 2009, CMS implemented the MIPPA provisions. The agency stated that exceptions will be established through notice-and-comment rulemaking to ensure transparency and opportunity for public input. The CMS rule also established a two-level process that CMS must go through to alter the six current protected classes of drugs as well as identify new protected classes. This process includes a first level of contractor review and a second level of expert panel review. CMS also announced that it "may further articulate [its] interpretation of the new statutory criteria" in future rule making. 74 Fed. Reg. 2884.

Use of "Off-Label" Indications

Pursuant to the newly issued Call Letter, Part D sponsors "will not be permitted to require an enrollee to try and fail drugs supported only by an off-label indication… before providing access to a drug supported by an FDA approved indication (on-label indication) unless the off-label indication is supported by widely used treatment guidelines or clinical literature that CMS considers to represent best practices." 2010 Call Letter, p. 64. This language shows a change in the policy, referred to as "fail-first," under which some Part D Plans reportedly require treatment with off-label drugs to fail for a patient before Part D sponsors will reimburse for using a drug that the FDA has approved for that specific use.

CMS's position on this policy in its 2010 Final Call Letter language is largely the same as it was in its draft Call Letter. The draft Call Letter stated that "[i]n the absence of widely used treatment guidelines or clinical literature, Part D sponsors will not be permitted to require an enrollee to try and fail drugs supported only by an off-label indication (an indication only supported in the statutory compendia) before providing access to a drug supported by an FDA approved indication (on-label indication)." 2010 Draft Call Letter, p. 57.

Medical Loss Ratio Disclosure

On the issue of medical loss ratio (MLR), the 2010 Call Letter leaves the possibility of reporting open for consideration in future contract years. In the February draft Call Letter, CMS requested public comments on this issue, and received many comments in response. CMS stated on the first page of its final 2010 Call Letter, that due to the issue's complexity, it will "continue evaluating methodologies for possible future implementation." 2010 Call Letter, p. 1.

Private Fee-For-Service plans

The 2010 final Call Letter describes changes to private fee-for-service (PFFS) plans made by MIPPA. The most significant of these is the provision stating that a Medicare Advantage plan cannot take advantage of "deeming" if there are "at least two" network-based plans operating in the area. Currently, providers may be "deemed" to have a contract with Medicare Advantage plans in certain areas so that they meet statutory requirements to participate in that geographic area. The 2010 Call Letter sets out a policy where beginning in plan year 2011, a PFFS plan operating in a county with at least two network-based plans will not be able to meet access requirements through the use of "deeming."

Coding Adjustment and MA Growth Percentage

After issuing the 2010 final Call Letter on March 30, CMS on April 6, 2009 issued the CY 2010 MA Capitation Rates and Payment Policies & CY 2010 Part D Payment Notifications. In this payment rate notification, CMS announces that it will for the first time make a "coding pattern differences adjustment" to Medicare Advantage risk scores for plan year 2010 to adjust for the observed differences in coding patterns that exist between MA plans and traditional fee-for-service Medicare. The announcement explains that the MA coding pattern adjustment factor will "adjust for the growth in MA risk scores that occurs above and beyond the average growth captured in the normalization factor." The adjustment will be applied across the board to all plans in a uniform 3.41% reduction of Part C risk scores in 2010.

Additionally, CMS announced that its final county rate MA Growth Percentage, or fee increase, will be 0.81% for elderly and disabled enrollees. This increase in MA payments is slightly more than what was proposed in the CMS 2010 Advance Notice issued in February, but smaller than it has been in recent years. In calculating the Growth Percentage, CMS took into account the 21% reduction in physician fee payment which is scheduled to take effect in 2010 unless Congress intervenes, as it has each year since 2002. CMS stated that its decision to take this scheduled reduction into account in its calculations is consistent with the Agency's longstanding practice to base the

projected growth percentage on the law as it exists on the date of the payment rate update announcement. In a posting on the CMS website, CMS also stated that "if Congress acts to override the physician pay cut, CMS will work with Congress to explore viable options for incorporating any changes in physician pay into the MA payments for CY 2010."

Conclusion

CMS's 2010 final Call Letter shows that the Obama Administration is taking a decidedly different approach toward Medicare Advantage Organizations and Prescription Drug Plans from that which the Bush Administration took. Medicare Advantage Organizations will need to take these changes into account in preparing bids for submission to CMS before June 1, 2009. We will continue to monitor this issue and will provide updates as necessary.

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