AMCP Academy of Managed Care Pharmacy®

January 13, 2014

Dr. Cynthia Tudor
Acting Center Director
Medicare Drug Benefit and C and D Data Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Part D Payment for Drugs for Beneficiaries Enrolled in Hospice, Memorandum December 6, 2013

Dear Dr. Tudor:

The Academy of Managed Care Pharmacy (AMCP) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) December 6, 2013 memorandum offering draft guidance and seeking comments on payment for medications under the Medicare hospice benefit. AMCP has concerns about the impact of the guidance on the terminally ill Medicare beneficiaries who receive hospice and their caregivers and families. AMCP believes that the provisions in the draft guidance will create unnecessary confusion for these vulnerable Medicare beneficiaries and may potentially create unnecessary financial burdens for them by seeking recoupment and repayment of hospice-covered medications mistakenly billed to the Part D program rather than Medicare Part A. The draft guidance also creates confusion regarding the responsibilities of the Medicare prescription drug program (PDP) sponsors and hospice providers with regard to coverage, coordination, and communication.

AMCP offers comments on the draft guidance and suggestions for potential resolution to some of these issues. AMCP suggests that CMS restructure the proposed process to allow for recoupment directly from the Medicare Part A program or from pharmacies and not hospice beneficiaries, their families, and caregivers. AMCP also urges that CMS delay implementation of this change from March 1, 2014, until it proposes a more specific approach to the recoupment process, use of an independent review entity, and other provisions related to coverage determinations through a formal notice and comment period.

AMCP is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's almost 7,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

AMCP recommends that CMS develop clear written guidelines for PDPs and beneficiaries regarding Medicare coverage for medications used in hospice. Currently, the standard is ambiguous and as a result many of the problems associated with inability to establish whether a medication should be billed to the Medicare hospice program or Part D arises at the point of sale at the pharmacy and thus medications are often mistakenly adjudicated to a PDP. As you know, hospice is classified as a Medicare provider, not a payer and therefore, the recoupment should be made from the Medicare Part A program, not a provider. The guidance suggests that rather than making payment adjustments and seeking recoupment from the Medicare Part A program, PDPs should recoup payment from the hospice entity, even though hospice is a Medicare provider and not a payer. The hospice provider may then seek to recoup payments from the beneficiary. AMCP does not support this approach because of the unnecessary burden and difficulties it presents to Medicare hospice beneficiaries, their families and caregivers. Thus, AMCP supports an alternative that would allow for recoupments from the Part A program or from pharmacies that are subject to clear, enumerated requirements that would streamline the process and eliminate this burdensome provision for beneficiaries.

The draft guidance also suggests that CMS will develop an independent review process to manage disputes involving hospice providers and PDPs. However, this process has not been clearly defined in the proposed guidance. Issues that remain unresolved in the guidance include: timing of cases, rules related to the hearing process, the enforcement process for final determinations; and any fees associated with this process. This new process requires more clarity and should not be considered in sub-regulatory guidance but rather through a formal notice and comment period so stakeholders can provide input based on their experiences. A formal notice and comment period would ensure that this issue has the proper force and effect of law and CMS oversight.

CMS would require that the hospice provide documentation related to medications not covered under the hospice formulary to the PDP. However, CMS has not issued guidance regarding the timeframe or requirements related to the provision of this documentation to PDPs. To ensure that a beneficiary receives hospice coverage, the hospice must file a notice of election (NOE) with CMS, but the timeframe for submission is unclear and not standard, AMCP would recommend 72 hours. CMS' own manual for processing hospice claims[1] states that the notice of election (NOE) must be filed "as soon as possible" and does not provide a standard timeframe. A delay in filing of a NOE may result in a delay in a PDP's receipt of a transaction reply report (TRR) that alerts a PDP to hospice enrollment. This delayed process would also restrict the ability of PDPs to establish prior authorizations (PA) on all medications covered under the hospice benefit and thus increase the likelihood that claims be unintentionally billed to the PDP rather than Medicare Part A. For these reasons, AMCP urges CMS to use its authority under Medicare Part A to establish a specific timeframe for submission of the NOE and other documentation to the Medicare program or a PDP. CMS should allow an opportunity for public comment on these timeframes.

The guidance also suggests that Part D coverage is available for medications not covered under the hospice benefit or not related to management of the terminal illness. CMS should consider establishing standards of review for hospice formularies that are similar to Medicare Part D requirements, including considerations for robust formularies and specific examples of medications

[1] CMS. Medicare Claims Processing Manual. Chapter 11, Processing Hospice Claims [rev. 7/26/2013). http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c11.pdf. Accessed January 10, 2014.

that do not relate to the terminal illness and thus should not be covered by the hospice benefit. For example, further clarity is necessary to establish;

- whether medications prescribed for a chronic condition prior to hospice election are excluded from hospice coverage because they are not related to management of symptoms associated with the terminal illness;
- whether medications taken for management of illnesses that develop after hospice election would be covered by Medicare Part A or Part D;
- timeliness of hospice responses to PA notices from PDPs; standards for PDPs to review documents sent by the hospice to the PDP
- whether a beneficiary is deemed to have creditable coverage for Medicare Part D during a hospice stay or whether the individual must re-enroll in the program after revocation of hospice coverage; and,
- address issues related to the level necessary for coordination between the PDP and hospice if hospice coverage is denied.

Again, as stated previously, these issues require formal resolution and regulatory oversight and thus are subject to public notice and comment.

Finally, AMCP is concerned that the amount of sub-regulatory guidance issued on this topic has led to great confusion and upheaval with regard to hospice coverage. Specifically, in three separate documents, CMS has offered conflicting direction: the 2014 Call letter instructed PDPs to recoup improper claims from pharmacies, an October 30, 2013, memorandum only recommended recoupment from pharmacies; and the December 6, 2013, guidance prohibited recoupment from pharmacies.[2] These guidance documents also provided differing instructions on the scope of analgesic and other categories of medications covered or not covered under the hospice benefits.[3] This confusion, combined with many unanswered questions, regarding oversight, processes, and communication between and among beneficiaries, PDPs, and hospice providers leads to the conclusion that formal notice and comment is necessary to ensure proper implementation and understanding of the provisions. Furthermore, plans and hospice providers should be given more time to prepare for these requirements and thus the implementation date of March 1, 2014, should be extended to the beginning of a plan year after the notice and comment process.

Thank you for considering AMCP's comments. AMCP looks forward to continued improvements in this area to ensure that terminally ill hospice beneficiaries receive access to necessary and appropriate medications in a timely manner. AMCP respectfully requests that CMS not transfer the "solution" of the problems with implementation of the current system to the patients being served by hospice. If you have any questions, please contact me at 703-683-8416 or erosato@amcp.org.

Sincerely,

Edith A. Rosato, R.Ph., IOM
Chief Executive Officer

[2] CMS website on hospice guidance documents. http://www.cms.gov/Center/Provider-Type/Hospice-Center.html. Accessed January 10, 2014.
[3] *Ibid.*