Summary of Medication Management Requirements in New CMS Conditions of Participation for Hospice Programs
June 2008

The Centers for Medicare & Medicaid Services (CMS) recently released revised Conditions of Participation (CoP) for hospice programs that participate in the Medicare and Medicaid programs. To access the CMS Final Rule that outlines the new CoP requirements, visit http://www.cms.hhs.gov/CFCsAndCoPs/Downloads/CMS3844F.pdf.

Effective Date

The new requirements are to go into effect 180 days from publication of the final rule in the Federal Register, which occurred on June 5; therefore, the implementation date should be December 2, 2008.

Background

The new requirements are part of the Conditions of Participation (CoP) set forth by the Centers for Medicare and Medicaid Services (CMS). Any hospice program that participates in the Medicare and Medicaid programs must comply with the CoPs. Compliance with these federal regulations is evaluated through a survey of the hospice by the state survey agency (periodically accompanied by federal surveyors) or by Joint Commission (if the hospice chooses to undergo Joint Commission accreditation). Hospices choosing Joint Commission accreditation will be evaluated against both Joint Commission standards and CMS CoPs.

In this CoP update, the first since 1983, only a portion of the CoPs was revised. The full CoPs for hospice programs can be found in Appendix M of the CMS State Operations Manual (available online at: http://cms.hhs.gov/manuals/Downloads/som107ap_m_hospice.pdf)

Consultant Pharmacist Services

In the revised CoPs, new medication-related services are required, above and
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beyond what was required in the previous (current until December) regulations. Consultant pharmacist services were previously required only for inpatient hospice facilities. The new requirements are broadened to include all hospice programs, which presents a new opportunity for consultant pharmacists to market their services and skills to hospices.

The new requirements state that the hospice’s interdisciplinary group must “confer with an individual with education and training in drug management as defined in hospice policies and procedures and State law, who is an employee of or under contract with the hospice, to ensure that drugs and biologicals meet each patient’s needs.” As part of the interdisciplinary team, consultant pharmacists might also be involved in reviewing the plan of care to determine whether the patient and/or family has and continues to have the ability to safely administer medications, which is a required activity of the interdisciplinary team based on the new CoPs.

CMS further states in their document that they expect most hospices to utilize a pharmacist to provide the medication-related consultation described above. Unfortunately, they stop short of actually requiring the hospice to utilize a pharmacist. However, the individual the hospice consults with must have “specialized education and training in drug management, including evaluating the effectiveness of drug therapies, identifying drug side effects, identifying actual or potential drug interactions, identifying redundant drugs, and taking appropriate corrective actions.” Keep in mind that the rule also states “all hospices must be able to demonstrate an individual’s knowledge, skills, and abilities in managing the use of drugs in accordance with accepted standards of practice and all applicable State and local requirements, including State licensure requirements.” The qualifications necessary for a pharmacist’s state licensure along with the academic and practical training in pharmacotherapy make pharmacists uniquely qualified to perform medication review activities; it sets pharmacists apart from other providers. This is important to mention when approaching a hospice about contracting to provide clinical services.

The CMS Final Rule also mentions pharmacy benefit management companies, which they state many hospices already contract with to provide drugs and pharmacist services to their patients. While other providers are not mentioned or recommended for performing medication review services, one can assume many hospice programs, for cost containment purposes, might attempt to utilize nurses or nurse practitioners to perform the medication reviews. Again, it will be important for pharmacists to communicate their credentials, skills, and value when marketing their services to a hospice.

In addition, the previous hospice CoPs required the hospice to employ or contract with a licensed pharmacist to advise the hospice on ordering, storage, administration, disposal, and recordkeeping of drugs and biologicals. Those requirements will continue and serve as additional services that a pharmacist should market to a hospice program.

Before beginning to consult to a hospice program, consultant pharmacists should
review Appendix M of the CMS State Operations Manual and the new CoPs, reviewing in particular any mention of medications, drugs, pharmacists, or pharmacy – but also reviewing other pertinent standards such as the plan of care, interdisciplinary group, etc.

Cost Estimate for Consultant Pharmacist Services

In the final rule document, CMS outlines the anticipated burden associated with implementing each new requirement, both from a financial and resource perspective. For the medication review services, they estimate no additional cost of the hospice if they use a pharmacy benefit management company, as they often provide both dispensing and consultative services by a pharmacist for a per diem rate comparable to what hospices, on average, are spending on medications per patient per day. For hospices who choose to utilize the services of an independent consultant pharmacist, CMS is estimating that an initial medication review upon admission would take a pharmacist 30 minutes to complete, on average. In addition, they’re estimating it would take a pharmacist 15 minutes per additional review necessitated by an update to the resident’s medications and/or care plan. Based on a median length of stay in hospice of 26 days, they are estimating that three reviews will be needed per patient per stay (one admission review and two update reviews). Therefore, their overall average cost estimate for an independent consultant pharmacist would be $56 per patient ($28 for admission review plus two update reviews at $14 each), which ultimately ends up totaling an average of $16,968 annually for all of a hospice program’s patients (assuming an average of 303 patients per hospice per year).

Chemical Restraints

Due to increased restraint use in the hospice setting, the revised CoPs address restraints for the first time. CMS uses a two-part definition of “restraint” that encompasses all types of restraints, both chemical and physical. The following is the portion of the definition dealing with drug or chemical restraints: “A drug or medication when it is used as a restraint to manage the patient’s behavior or restrict the patient’s freedom of movement and is not a standard treatment or dosage for the patient’s condition.” If restraints are used, certain stipulations must be met, including rationale in the plan of care, a physician’s order, and other requirements. Discussion of restraints is included in Section 418.110 (m) of the regulations.

Controlled Medications

While the previous CoPs required hospice programs to have a policy for the disposal of controlled drugs maintained in the patient’s home when those drugs have been discontinued by the physician or are remaining at the time of death, the new CoPs broaden the responsibilities associated with managing controlled medications.
The new CoPs still require policies and procedures for the management and disposal of controlled medications in the patient’s home, but they additionally require the hospice to provide a copy of those policies and procedures to the patient or family/representative and to discuss them. They must document the provision and discussion of the policies and procedures in the patient’s chart.

If the hospice is an inpatient facility, additional policies and procedures for controlled substance are required related to storage and record-keeping.

**Dispensing Pharmacies**

Pharmacies that dispense medications to hospice residents should become aware of the new CoP requirements, especially if they are supplying medications to an inpatient hospice facility. In particular, dispensing pharmacies should be aware of the labeling, storage, disposal, and controlled medication requirements with which hospice programs must comply, most of which are covered in Section 418.106 – Condition of Participation: Drugs and Biologicals, Medical Supplies, and Durable Medical Equipment.

In addition, pharmacies might be interested in the statistics presented in the Final Rule document outlining the average drug spend per hospice patient per day. Here is what the document says:

“We estimate that an average hospice already spends $123,842 annually to provide drugs and biologics for its patients ($15.72 per patient day (dollar figure is not adjusted for inflation) for drugs and biologicals based on 2001 Millman USA Report titled, "The Costs of Hospice Care: An Actuarial Evaluation of the Medicare Hospice Benefit" and consistent with the 2002 NHPCO National Data Set).”

**Durable Medical Equipment (DME)**

Based on the new rule, hospice programs must comply with several new requirements regarding durable medical equipment. Hospices, either directly or under contract with another company, will be responsible for ensuring the maintenance and repair of durable medical equipment in a manner that conforms to manufacturer recommendations. If no manufacturer recommendations exist for a piece of equipment, then repair and routine maintenance policies and procedures are to be established by the hospice. The hospice also must provide instruction to the patient, family, and all other caregivers in the safe use of equipment and supplies. Likewise, the hospice must ensure that the patient, family, and other caregivers can demonstrate the safe use of such equipment and supplies to the satisfaction of hospice staff. The new requirements also state that the hospice may only contract with a durable medical equipment supplier that meets the Medicare Durable Medical Equipment, Prosthetics, Orthotics Supplies (DMEPOS) Supplier Standards (available online at:}
When supplying durable medical equipment to a hospice program or hospice patient, be sure it is clearly outlined upfront as to who will take on responsibility for equipment maintenance and patient/caregiver education. If a hospice program/facility already has a contract with a pharmacy for DME, they are likely to look to the pharmacy for such maintenance and education. Add those specifics to your contract, if they are not already included. If your pharmacy happens to supply equipment to individual hospice patients but does not have a service contract with the hospice program/facility, be sure to talk with the hospice program to find out how they wish to handle equipment and maintenance in those situations. In many cases, the pharmacy staff are likely meeting many of these requirements already when furnishing durable medical equipment; it’s just a matter of the hospice having proper documentation of such activities.

Role of Drug Reviews in Initial and Comprehensive Assessments

The new CoPs require an initial assessment along with a comprehensive assessment of each hospice patient. The initial assessment is meant to be a brief assessment, conducted within the first 48 hours of admission, to determine the patient’s immediate care needs. It will most certainly mention current medications; however, there is a not a specific requirement for a medication review or other medication-related service at that time. The comprehensive assessment, on the other hand, is to include a medication review of all the patient’s prescription and over-the-counter medications, herbal remedies, and other alternative treatments that could affect medication therapy. This review should include “identification of the following:
- effectiveness of drug therapy,
- drug side effects,
- actual or potential drug interactions,
- duplicate drug therapy, and
- drug therapy concurrently associated with laboratory monitoring.”

While the CoPs do not specify which providers or disciplines must complete the assessment, CMS does state in their discussion of comments received that “the hospice’s interdisciplinary group, in conference with an individual who has specialized education and training in drug management, such as a pharmacist, will be required to address these issues in the patient’s individualized hospice plan of care.”

Inpatient Hospice Facilities

Inpatient hospice facilities must meet additional requirements related to medication management, including having policies and procedures for dispensing, administration, and controlled medications. Many of the
requirements remain the same or are similar to previous requirements; any changes constitute minor clarifications.