

Overview of Short-Cycle Dispensing for Long-Term Care

Beginning January 1, 2013, the Centers for Medicare and Medicaid Services (CMS) will require all pharmacies dispensing prescription drugs to long-term care (LTC) facilities (skilled nursing facilities / nursing homes) under Part D Plans (PDP) and Medicare Advantage plans (MA-PD) to dispense solid oral doses of brand-name drugs in no greater than 14-day increments. This is a notable change for 2013 for pharmacies serving Medicare and Medicaid-certified nursing homes and skilled nursing facilities. A summary of the regulation is outlined below.

14-Day Dispensing for Solid Oral Doses of Brand-Name Drugs

CMS will require all pharmacies (including not only closed-door LTC pharmacies, but also retail pharmacies and mail order pharmacies that dispense to LTC facilities) to dispense solid oral doses of brand-name drugs to residents of LTC facilities in 14-day-or-less increments. Two types of solid oral branded medications are excluded from the requirement: antibiotics that are for short-term treatment of an acute infection and drugs that are dispensed in their original container as indicated in the Food and Drug Administration Prescribing Information or those that are customarily dispensed in their original packaging to assist patients with compliance (for example, oral contraceptives). CMS has specifically chosen to include controlled substances under the short-cycle dispensing requirements, therefore brand-name, solid, oral doses of controlled substances must be dispensed in 14-day-or-less cycles. The 14-day requirement does not apply to non-solid oral brand-name drugs, such as liquids, inhalers, topicals, and etcetera. It also does not apply to generic medications.

Settings: this regulation does not apply to settings such as assisted living facilities, group homes, ICF/MRs, IMDs, and I/T/U pharmacies.

Dispensing Technique

Part D plans must permit the pharmacy to implement uniform dispensing techniques selected by each LTC facility, and may not require the pharmacy to use a different packaging system or technology than that selected by the pharmacy in collaboration with the facility. CMS has defined "dispensing

methodology" as both the packaging system (for example, punch cards, envelopes, or strip packaging) and the dispensing increment (for example, 14-day, 7-day, 2-2-3, daily, or automated dose dispensing). In other words, CMS permits for the facility to work with the pharmacy to choose the days' supply dispensed and the specific type or types of packaging to be used to dispense Part D drugs. The short-cycle regulation applies whether the pharmacy provides medications for one resident in the nursing home or all residents (covered under Part D or Medicare Advantage plans).

Billing

The new requirement will change the process for billing nursing home claims. NCPDP billing and clarification transaction codes will be required and NCPDP transaction codes will be used to collect data on dispensing methodology.

For 2013, CMS will require that Part D sponsors report three new fields on the PDE:

1. Patient Residence Type*
2. Pharmacy Service Type*
3. Submission Clarification Code (SCC) – subject to short cycle requirements

*For 2013, a valid Patient Residence and Pharmacy Service Type will be required on PDEs with a date of service of February 28, 2013 or later for all beneficiaries in a nursing facility, assisted living facility, group home, intermediate care facility for the mentally retarded, or hospice facility when the drug is dispensed under the pharmacy's contract with the facility. Reporting of these fields is required regardless of whether the drugs dispensed are generic or brand, regardless of the pharmacy type, and regardless of whether short-cycle dispensing was applicable. In those instances in which short-cycle dispensing is required (i.e., solid oral doses of brand-name drugs dispensed to enrollees in LTC facilities) the PDE must also include the appropriate Submission Clarification Code which indicates the dispensing method (14-day; 7-day; 3-4 day; 2-2-3 day, etc.).

You are encouraged to direct specific questions about billing codes to your software vendor.

Dispensing Fees

Though CMS is prohibited from intervening in negotiations between pharmacies and Part D plans to directly affect the contracted amount of dispensing fees, they state that it is reasonable to expect that dispensing fees be adjusted based on the newly proposed requirements. (For purposes of scoring the rule, CMS made the assumption that dispensing fees would double.) CMS also clarified the definition of "dispensing fees" by including the salaries of pharmacists and other pharmacy workers as reasonable costs for any pharmacy as well as the costs associated with the data collection of unused Part D drugs. Dispensing fees should take into consideration the number of dispensing events in a billing cycle, the acquisition and maintenance costs associated with the type of dispensing methodology utilized, and,

with respect to Part D drugs dispensed in LTC facilities, the techniques to minimize the dispensing of drugs that go unused. Dispensing fees may also take into account restocking fees associated with return for credit and reuse in LTC pharmacies, when return for credit and reuse is permitted under State law and is allowed under the contract between the Part D sponsor and the pharmacy.

Copayments

Copayments should be billed on the first dispensing event of the month, the last dispensing event of the month, or prorated with each dispensing event. However, regardless of the number of incremental dispensing events, the total cost sharing cannot exceed the total cost share imposed for the drug if the 14-day requirements did not apply.

Reporting Requirements

CMS originally indicated they would require pharmacies to report unused medications to the Part D plans. However, in May 2012, CMS confirmed that they will not require unused drug reporting when short-cycle dispensing requirements begin on Jan. 1, 2013. Based on industry feedback, CMS agreed this would be a burdensome process and has determined there are other data elements they can utilize to compile these reports.

References

- The regulation can be found in the Code of Federal Regulations, [42 CFR 423.154](#) (Appropriate dispensing of prescription drugs in long-term care facilities under PDPs and MA-PD plans).
- Provisions of the final regulations and analysis of and responses to public comments by CMS can be found by clicking [here](#).
- The Comprehensive NDC Structured Product Labeling (SPL) Data Elements File (NSDE) is available at:

<http://www.fda.gov/forindustry/datastandards/structuredproductlabeling/ucm240580.htm>

Users can download the list in an Excel file. The list contains information for drug products in final marketed form. It is updated each business day and includes marketing category information for brand and generic drugs (NDA, ANDA, BLA, etc.). Note that CMS began using the NSDE file to edit all Prescription Drug Events (PDEs) starting September 1, 2012.