

50.4 - Home Infusion Pharmacy Access

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

In order to meet the requirements for adequate access to home infusion pharmacies, Part D sponsors must deliver home infusion drugs to enrollees within 24 hours of discharge from an acute setting, unless the next required dose, as prescribed, is required to be administered later than 24 hours after discharge. To ensure Part D sponsors can provide such access, as part of their initial pharmacy access submissions, and through Part D annual reporting requirements (Information Collection Requirements (ICF) OMB 0938-0992), each Part D sponsor must provide a list of all contracted home infusion pharmacies licensed/legally able to serve in all State(s) and/or territories in the service area under each CMS pending contract number. The

pharmacy list must be submitted using the CMS template, which includes NCPDP/National Provider Identifier, pharmacy name, address, and all States and/or territories licensed in/legally able to serve.

CMS conducts an outlier analysis using these home infusion pharmacy network submissions to evaluate the robustness of home infusion pharmacy networks of all active Part D sponsors. As part of the Part D application, initial applicants to the Part D drug benefit program must demonstrate access through submission of their home infusion pharmacy networks, which must be no less robust than these outlier levels for their pending service area(s) as identified in Appendix [I](#). CMS will evaluate access for existing sponsors through a modified outlier approach which looks at both the number of pharmacies relative to the established outlier level combined with evidence that the existing sponsor is meeting the 24 hour delivery standard for its enrollees.

Network robustness is assessed within contract types (e.g., PDP, Regional Prospective Payment Organization or RPPO, and MA-PD). Outliers are those contracts that are in the lowest 25th percentile in terms of the number of contracted home infusion pharmacies within a given state. In other words, 75 percent of all similarly-situated Part D sponsors have a more robust home infusion pharmacy network than the outliers in the lowest 25th percentile. For organizations whose service area comprises an entire state, Appendix [I](#) provides the minimum number of home infusion pharmacies required to surpass the 2010 Reporting Requirement and 2011 Part D Application outlier level. Organizations operating in a service area smaller than an entire state may use the provided ratios of the number of home infusion pharmacies to the number of beneficiaries in the state and apply it to the number of beneficiaries in the organization's service area to calculate the minimum required number of home infusion pharmacies for that particular service area.

CMS does not expect Part D sponsors to provide or pay for supplies, equipment, or the professional services needed for home infusion therapy. Part D sponsors' contracted network pharmacies must be able to:

- Deliver home infused drugs in a form that can be easily administered in a clinically appropriate fashion;
- Provide infusible Part D drugs for both short-term acute care and long-term chronic care therapies;
- Ensure that the professional services and ancillary supplies necessary for the provision of home infusion therapy are in place before dispensing home infusion drugs, consistent with the quality assurance requirement for Part D sponsors described in [42 CFR 423.153\(c\)](#); and
- Provide covered home infusion drugs within 24 hours of discharge from an acute setting, unless the next required dose, as prescribed, is required to be administered later than 24 hours after discharge.

While Part D sponsors remain ultimately responsible for complying with all Part D requirements, they are also permitted to delegate their responsibilities to plan contractors, such as network pharmacies. Part D sponsors may contractually delegate the responsibility for ensuring timely delivery of home infusion drugs to their network pharmacies provided they meet the

requirements of [42 CFR 423.505\(i\)](#) regarding relationships with pharmacies or other providers, related entities, contractors, subcontractors, and first tier and downstream entities.