

Attachment A

CMS Response to Public Comments Received for CMS-10834

The Centers for Medicare and Medicaid Services (CMS) received two comments. Responses are below.

Comment #1:

Comment:

The commenter, a pediatric nurse practitioner (PNP) student, interprets the estimate of 52 burden hours to mean that each prescriber would need to spend more than 52 hours completing a waiver application. The commenter also expresses concern that the 306 estimated waivers represent an excessive burden for individual practitioners, particularly those in small, independent, or rural practices. The commenter additionally raises questions about applicability to pediatric settings, and notes concerns regarding waiver duration and the renewal process.

Response:

We appreciate the commenter's feedback and the perspective shared as a pediatric nurse practitioner (PNP) student. The figure 306 represents the estimated number of individuals nationwide who are expected to submit a waiver application each year. It does not reflect the burden on any single practitioner or practice.

Similarly, the 52 total burden hours shown in the Supporting Statement represent the combined annual burden across all respondents. Each waiver application is estimated to require approximately 0.17 hours (about 10 minutes). When multiplied by the projected 306 respondents, this results in an aggregated annual burden of 52 hours.

We also note the commenter's concerns regarding smaller or resource-limited practices. CMS finalized a small prescriber exemption, which reduces burden for practices with low volumes of Medicare Part D prescriptions. In addition, the EPCS requirements apply only to Medicare Part D controlled substance claims. Because very few pediatric patients are enrolled in Medicare Part D, pediatric-specific prescribing workflows generally fall outside the scope of this requirement.

The commenter also raised questions regarding waiver duration and the renewal process. Information on waiver timeframes, renewals, and related processes is available on the [CMS EPCS Program webpage](#), which serves as the central resource for guidance and program updates.

Comment #2:**Comment:**

The commenter supports CMS's proposal to require electronic prescribing of controlled substances under Medicare Part D, citing benefits for fraud reduction and improved accuracy. The commenter also notes that smaller or resource-limited practices may face challenges adopting the required technology and recommends that CMS provide support or consider a phased transition.

Response:

We appreciate the commenter's support for implementing electronic prescribing of controlled substances. CMS agrees that electronic prescribing enhances program integrity and patient safety by reducing fraud, minimizing errors, and ensuring secure transmission of prescriptions.

CMS also acknowledges the commenter's concerns regarding smaller or resource-limited practices. CMS considered these challenges in prior rulemaking and established a small prescriber exemption, which reduces burden for providers who write a low volume of Medicare Part D controlled substance prescriptions. This exemption is intended to address the unique operational constraints that small practices may face.

In addition, CMS implemented a phased compliance approach to provide additional time for system upgrades and workflow adjustments. This approach helps ensure that providers have adequate time to prepare for the transition while the program continues advancing the benefits of electronic prescribing.

CMS appreciates the commenter's recommendations and will continue implementing the EPCS requirements in a manner that supports provider readiness and promotes safe, modern prescribing practices.