CMS-10954 Response to Public Comments

The following is a summary of the comments received and the responses.

1) Comment: A commenter stated that the burden estimate was generally appropriate once the proposed web app and FHIR® interfaces were available.

Response to comment: We thank the commenter for this feedback. Our burden estimation process was based on field (beta) test data, and we intend it to reflect typical clinical practice. We will monitor and update burden estimates associated with the new PRA package for the IPF-PAI as needed as IPFs gain more experience reporting IPF-PAI data.

2) Comment: Several commenters stated that field (beta) test results could not be applied to the final instrument and that the 14.7-minute estimate understated complexity.

Response to comment: With respect to time-to-complete estimates, the field (beta) test informed the burden estimate by providing total times for data collection across the entire test instrument, which we used to calculate the average per-assessment item part estimate. We maintain that our time estimate for each assessment item part is valid; we used only the portions of the field (beta) test in which IPF staff were assessing real patients.

3) Comment: Many commenters stated that CMS' burden estimate focused too narrowly on item completion time and understated the real-world effort needed for EHR reconfiguration, vendor work, staff training, workflow redesign, data correction, internal validation, quality assurance, FHIR® or iQIES submission, reporting steps, interoperability needs, and ongoing compliance monitoring. Several commenters stated that treating the IPF-PAI like a single IPF Quality Reporting Program measure understated the number of assessments.

Response to comment: We recognize that there will be costs associated with implementing the IPF-PAI that are not accounted for in these estimates of collection of information. Consistent with PRA requirements, our collection of information estimates are limited to recurring data collection costs. These estimates were calculated using data collected during the field (beta) test in which IPF clinicians assessed real patients. These estimates do not extend to workforce training and other start-up costs, nor to any data monitoring activities that IPFs may choose to conduct. We note that the option of automated or semi-automated reporting using FHIR® APIs, for IPFs that have or develop that capability, is likely to reduce actual collection of information burden. We acknowledge the systems and data extraction challenges that facilities may face in their initial implementation of the IPF-PAI. We took these challenges into account in our decision to develop FHIR APIs to support the collection and reporting of the IPF-PAI. We understand that the transition to automated data reporting via the FHIR APIs will take time, and that IPFs may need to integrate IPF-PAI assessment items in their EHRs and in their clinical workflows in a way that will avoid an ongoing need for manual data extraction. We note that we are providing the Patient Assessment Reporting Interoperability Tool (PARIT), the free web app for data submission, as an interim solution for IPFs that are not yet ready to adopt EHR-

integrated technical solutions for data collection and reporting. We intend to provide robust training, technical documentation, and technical help desk support to help IPFs and health IT vendors, and staff understand and operationalize the extraction of EHR data and submission required by the IPF-PAI. In addition, we are finalizing a delay in mandatory reporting, to July 1, 2028, and allowing IPFs three quarters of voluntary data submission beginning October 1, 2027. We intend for this period to allow IPFs more flexibility on when and how they integrate the IPF-PAI into their workflows and systems in a way that minimizes burden.