Appendix

We received several comments during the public notice and comment period for the Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-facilitated Exchanges, and Health Care Providers proposed rule (84 FR 7610). The summary of the comments and response to the comments is noted below and is also contained in the final rule.

Comment: Some commenters expressed concern that the Centers for Medicare & Medicaid Services (CMS) underestimated the complexity of implementing the application programming interface (API) requirements and did not agree with the agency's estimation that the API implementation is a one-time cost. These commenters noted that additional costs include: the costs to contract with third-party applications, the costs of ongoing education, and the cost of answering questions from members about data and errors. Commenters argued that the adoption of the proposed API requirements significantly add to overhead costs and will increase costs for providers and payers, rather than facilitate information exchange and better care for patients. One commenter estimated a range of between $1 million and $1.5 million to implement the API requirements, with an additional $200,000 to maintain the API. Another commenter argued that the costs of implementation could be as high as four times the estimates CMS provided.

Response: We thank commenters for their input and understand their concerns associated with the cost required to implement the requirements of this final rule. We understand that our estimates regarding the implementation of the API provisions may vary depending on a number of factors, including, but not limited to, a payer's current knowledge of and experience with implementing Fast Healthcare Interoperability Resources (FHIR)-based APIs, and whether an impacted payer will develop this technology in-house or seek a third-party contractor to support this effort.

To further develop our cost estimates, we reviewed the cost estimates associated with updating Blue Button from Blue Button 1.0 to 2.0 to include a standards-based API, similar to the requirements of this final rule. This update was estimated at $2 million. However, we believe that the estimates associated with updating the existing Blue Button 1.0 to a standards-based API for Blue Button 2.0 do not accurately represent the costs for payers impacted by this final rule. Blue Button 1.0 was developed across several federal agencies, including the Departments of Defense, Health and Human Services, and Veterans Affairs, with a capability to allow beneficiaries online access to their own personal health records, such as the ability to download PDF documents. Unlike the standards-based APIs required under this final rule, Blue Button 1.0 was not originally developed with a prescribed set of standards that allow for third-party apps to connect and retrieve data via an API. The estimates for Blue Button account for upgrading an existing technology platform that was not originally developed to allow third-party app access via an API, which we believe adds additional cost that may not impact all payers under this final rule. Additionally, we note that costs related to federal procurement and the need to engage multiple contractors to implement the updates to Blue Button, while at the same time maintaining access to the original system, caused the cost of implementing standards-based APIs

for Blue Button 2.0 to be higher than those costs for payers impacted by this final rule. Therefore, while we believe that the estimates for upgrading Blue Button from 1.0 to 2.0 are not truly representative of the cost to implement the standards-based API required by this final rule, nonetheless they are valuable in further informing our cost estimates.

As noted above, we did receive one comment that suggested a cost range between $1 million and $1.5 million to implement the API requirements of this final rule, with another commenter indicating a four-fold increase in costs relative to the estimates included in the proposed rule. While disagreeing with our bottom line, these commenters did not provide where in our detailed analysis we underestimated costs. For example, it is unclear if the commenters were including voluntary provider costs, or other costs when calculating the dollar amounts for compliance. Therefore, without specific examples of additional costs that need to be accounted for in this impact analysis, we believe that our estimates are reasonable. To address commenters' concerns regarding ongoing costs, we remind readers that we specifically are accounting for a cost of $157,656[1] per organization, for costs throughout the year to include: allocating resources to maintain the FHIR server, which includes the cost of maintaining the necessary patient data, and perform capability and security testing.

However, in an effort to take into account the additional information that commenters presented regarding our costs estimates, and understanding there are many factors that may influence the cost of implementing these policies, as noted above, we are adjusting our cost estimates to reflect a range instead of a point estimate. We believe that our cost projections for an initial one-time cost to implement the API requirements of this final rule of $718,414 per organization, reflecting 6 months of work by a team of ten professionals, can now serve as a minimum estimate; in other words, we do not believe it is technically feasible to implement the requirements of this final rule in less than 6 months. For a primary estimate, we have increased our cost estimates by a factor of 2 to account for cost variation. We note that using this factor of 2, the cost per organization is consistent with the commenter stating a $1 million to $1.5 million per organization cost. For a high estimate we have increased our cost estimates by a factor of 3. Although, one commenter noted a factor of 4 should be included, all other information available to us, including the commenter who noted a range between $1 million and $1.5 million, and our estimates for upgrading Blue Button, a factor of 4 does not appear to be reflective of the costs for implementation and represents more of an outlier for cost estimating purposes. As shown in section XIII. of this final rule, we have revised down our estimate of affected individual market enrollees from 76 million (all commercial market enrollees) to 17.5 million (those individual market enrollees directly affected by this final rule). This reduction by a factor of 4 (76 million former estimate/ 17.5 million revised estimate) raises the cost per individual market enrollee per year by a factor of 4 consistent with the commenter's suggested factor of 4. This factor of 4, however, only affects cost per enrollee per year; it does not affect total costs as calculated in Table 2.

Additionally, we note that as part of our original estimated costs associated with the annual burden of the requirements of this final rule, we accounted for additional capability testing and long-term support of the APIs, increased data storage needs, such as additional servers, or cloud storage to store any additional patient health information, and allocation of resources to maintain the FHIR server, and perform capability and security testing. Therefore, our estimates related to the annual burden account for the ongoing cost, and we are not providing additional estimates for maintenance as this is already factored in.

[1] Specifically, this value is $157,656.60.