Dear Secretaries:

Thank you for the opportunity to comment on the referenced Request for Information (RFI). The HL7® Da Vinci Project and its membership appreciate the recognition and consideration of the HL7 FHIR® Da Vinci Patient Cost Transparency (PCT) Implementation Guide (IG). As noted in the RFI, we started to develop the IG in 2021 addressing interactions between a provider and payer to obtain estimates for anticipated services to be rendered. We completed our initial ballot in January 2022. Currently, we are working to complete the ballot reconciliation process and are targeting Standard for Trial Use 1 (STU1) publication in early 2023. The IG has been successfully tested at five Connectathons to date and has an active stakeholder community.

Putting patients at the center of their care and empowering them with information to make informed decisions is a primary driver for all Da Vinci Project work. The PCT use case provides a meaningful opportunity to continue our focus on solving interoperability challenges between payers, providers, and patients by developing the technological tools providers and payers can use to help them best inform patients about the potential cost of their upcoming care. The Da Vinci Project is focused on how FHIR APIs can best support getting the right information to the right place at the right time to improve outcomes and overall value. To this end, we focus our response to this RFI on those questions most relevant to the use of FHIR and how FHIR APIs, generally, and the HL7 Da Vinci PCT IG, specifically, could support meeting the legal, and future regulatory, requirements. While we believe it is important for providers, payers, and patients – and the vendors who support them – to comment directly on the policies and business processes that will most impact them, we do share some broader insights provided through our community discussions over the last two years to support the Departments in their work.

A FHIR-Based Solution

Da Vinci members look forward to the additional clarity future regulation will provide. However, based on the known legal requirements, the Da Vinci Project and its members feel strongly that using FHIR, and specifically leveraging the HL7 Da Vinci PCT IG, would provide significant benefit. It would provide a standards-based structure for a repeatable process providers and payers could use to facilitate the submission of a GFE from a provider to a payer and an AEOB back to the patient, and optionally back to the provider. Using the HL7 Da Vinci PCT IG aligns this process with the current claims process, which is a known information exchange, helping maintain important efficiencies and limiting some of the
burden of what will be significant work to update back-end business processes and technology to generate the GFE on the provider side and the AEOB on the payer side without the benefit of all of the information that is known when a service is complete and an actual claim is generated.

We do note, however, that although the FHIR transaction itself can be “real-time,” and in scope of the HL7 DaVinci PCT IG, the processes necessary to create the GFE and the AEOB are out of scope for phase one of the IG and may not be “real-time,” particularly to start, for most providers and payers for most services, i.e., when involving multiple services across multiple providers.

The tight turnaround time required per the legislation for the provider to supply the GFE to the payer and the payer to provide the AEOB to the patient, has raised concerns in the community, especially early in implementation given the current state of highly, non-integrated source systems that would supply the service, fee, and cost-sharing information necessary for both. The use of FHIR and the HL7 Da Vinci PCT IG can support the “real-time” provider-payer interaction once a GFE is available from the provider, but “real-time” support for the entire end-to-end workflow from initiating the creation of the GFE to sharing the AEOB with the patient is not at this time expected to be “real-time” in most cases.

We do appreciate that not all providers and payers, especially some small and rural providers and payers, may be ready or able to leverage FHIR at this time. However, given the number of HHS, and specifically CMS, initiatives that are current requiring and/or promoting the use of FHIR APIs, more and more providers and payers are using FHIR or preparing to use FHIR for at least one use case. And, considering the synergies between the HL7 Da Vinci PCT IG and other IGs, such as the HL7 CARIN for Blue Button IG, which is also being used for the CMS Patient Access API, we do believe the Departments should encourage the use of the HL7 Da Vinci PCT IG in regulation to support this use case. We do suggest a phased-in approach to the use of an API to give providers and payers the needed time to rework their business processes and systems and, most importantly, to solidify these processes and systems in a way that provides patients with the most accurate, timely, and useful information.

**A Phased-In Approach**

Providers and payers are learning from their experience with the uninsured/self-pay GFE requirements. They are seeing patients delay or forgo care due to inaccurate estimates. The most important thing is that patients get as accurate an estimate as possible and trust the process and system and understand that it is in fact just an estimate based on the information known at that single moment in time. A phased-in standards-based approach could help providers, payers, vendors, and patients all get real world experience with the process, and it could help manage expectations and build the trust and literacy necessary for this process to add real value to patients.

As one part of a phased-in approach, we suggest leveraging FHIR for less complex services – where there is one provider or facility involved that would need to submit a single GFE to the payer to create the AEOB, such as an office visit. The community has raised several concerns regarding the burden on a convening provider or facility to identify all the appropriate co-providers/facilities, collect all their GFEs, and get them to the payer in the designated timeframe. For phase one of the HL7 Da Vinci PCT
IG, we do not yet support the collection of GFEs by the convening provider via FHIR, though if this is something regulation ultimately requires, it is something we could look to support in phase two of the IG, which we will begin work on in 2023. As much as providers and payers want to be sure patients have a complete estimate and clear picture of their planned care, at this time there is a need to minimize the burden on the convening provider and evaluate the technological solutions, including cost implications, that could support them.

For payers, there are challenges to taking in a bundle of multi-provider GFEs and creating a single AEOB, and there is a separate set of challenges when GFEs for the same period of care are sent separately by the multiple providers or facilities involved. Payers are largely planning to run the GFEs through a partition of their adjudication system as if they were claims and so each GFE from each co-provider or co-facility will essentially be treated as an independent claim. In phase one of the HL7 Da Vinci PCT IG, each GFE from each involved provider or facility can be included in a GFE Bundle where each GFE represents a claim from a billing provider (either institutional or professional). When this is received by the payer, they can use the IG to generate an AEOB bundle, which supports multiple AEOBs, each addressing one or more GFEs. This aligns with how claims are processed today to produce post-service Patient EOBs. For phase two of the IG, we are evaluating adding an “AEOB summary” to help patients better understand the interplay of multi-provider, multi-specialty services within a period of care, particularly how accumulators have been accounted for as part of the estimate process at that specific moment in time.

When multiple GFEs are sent separately to a payer from different providers/facilities for the same period of care, there are also challenges. If the payer does not receive information regarding which GFEs are for the same period of care, they will not know to consider them together for the purposes of creating the most accurate AEOB possible. For instance, they will not be able to appropriately account for accumulators. The phase one HL7 Da Vinci PCT IG can accommodate a “linking identifier” in the GFE so that the payer can know which GFEs are part of a single period of care. To have this included on all relevant GFEs, there is again burden to make the linking identifier known to all involved providers in a short timeframe. The second challenge is that payers will not know when they have all the GFEs for a period of care without receiving a count of the expected total. This is something the phase two HL7 Da Vinci PCT IG could accommodate. However, it adds burden to the convening provider/facility to collect and communicate this information to the payer.

If payers know which GFEs are part of a single period of care and how many GFEs are part of that period of care, this is valuable information that can assist the payer in putting together a more accurate estimate as it better supports having accumulators appropriately addressed. This will require additional coordination, however, and open questions remain. One question is what if a payer does not receive all expected GFEs in the timeframe needed to meet legislative requirements? Should the payer send an incomplete AEOB and include a message to the patient that the estimate is incomplete, and the estimate is not fully accurate? What if a GFE is received just after an initial AEOB is sent to the patient? The phase two HL7 Da Vinci PCT IG could accommodate a way to indicate if an AEOB is an update of a previously sent AEOB. In this way a patient could better understand iterative AEOBs, and how they relate to one another. But, this is still a burden on all patients, providers, and payers. Such
additional complexity will require time to fully work through to ensure appropriate business processes and technology are in place.

Starting with less complex services that involve a single provider or facility and phasing in more complex services including co-providers and/or co-facilities would provide the industry time to work out the needed business processes and allow us to ensure the best technological supports are available to help implement these new processes given the excessive burden attempting to complete this process manually would be per our members.

We also suggest that as one part of the phased-in approach, the Departments only consider requiring a GFE and AEOB for a scheduled service and encourage the use of the shopping tool required in the No Surprises Act or the comparison tool included in the CMS Transparency in Coverage final rule (CMS-9915-F) for estimate requests from the patient. For our current phase one HL7 Da Vinci PCT IG, the trigger to start the process is when a provider submits a GFE to a payer via a FHIR API. If a patient requests an estimate from a payer, the payer would need to request a GFE from the relevant provider. At this time, the IG does not support the payer reaching out to a provider for a GFE. Certain information required in the GFE per the law and necessary to generate an accurate AEOB will not be known if there has not already been some level of interaction with the person seeking care, more likely to have happened by the point of scheduling than if a person not previously seen by a provider or facility simply requests an estimate. Focusing on scheduled services will allow us to leverage more of the existing claims adjudication process to help reduce the burden on providers and payers to produce the required GFE and resulting AEOB. Providers and payers would like to reuse as much of their current billing process as they can so they are not building two separate systems when the estimated service is ultimately going to be a billed service in most situations. Providers and payers have also noted they are concerned it would be too burdensome and expensive to try to produce a GFE and AEOB for a “shopping” request.

Finally, as part of a phased-in approach, the Departments could consider combining the PCT use case with other FHIR API requirements. For instance, in our development of the HL7 Da Vinci PCT IG, we have been working closely with the HL7 CARIN for Blue Button team to ensure alignment. To this end, the HL7 Da Vinci PCT IG was developed with harmonization to the HL7 CARIN for Blue Button IG and Patient Access API as an explicit goal. This should significantly reduce the burden on implementors.

**ONC Health IT Certification and Incentives**

The Departments also ask about availability of certification criteria under the ONC Health IT Certification Program for use by payers, or health IT developers serving payers, to help to enable interoperability of API technology for PCT. At this time given that the systems being used to generate a GFE on the provider side and create the AEOB on the payer side are not generally IT certified by ONC, members are unsure this will be a valuable incentive. If and when, over time, provider practice management systems and payer payment systems are more likely to be certified IT, this could be considered, but at this time it does not seem to be a strong incentive or support. It is also important that prior to considering such certification, the capability being considered is ready for national level, scaled deployment using a demonstrated, mature standard.
We do believe that using the HL7 Da Vinci PCT IG has the opportunity to reduce burden on providers and payers and provides an opportunity for patients to get their AEOB in a way that will be most meaningful and actionable to them, such as via the Patient Access API. As such, a valuable incentive may simply be the potential for reduced burden.

**Cost and Burden**

The Departments asked about the time and cost of building versus buying an API, but per our members, providers will look to their existing vendors and the average provider will not know if or which API is being leveraged. Payers, too, will work with existing vendors or build this additional use case internally if that is consistent with their current work to implement FHIR. The real question for Da Vinci members isn’t the cost of buying versus building an API, it is the cost of attempting to meet these requirements via a manual process versus an automated one. The consensus among our members is that executing this use via a manual process will be prohibitively expensive, and thus a standards-based technological solution is necessary. One payer member’s internal determined it would take approximately 450 staff to touch these estimates manually and return the AEOB per the timing requirements without support of technology. Other members have noted the real burden is the need to update the backend business processes and systems to accommodate these new requirements. As such, the use of standards-based technology is an incentive to help address some of the burdens identified by the community understanding that the real burden is related to needed internal process updates for many providers and payers, as well as the need to accomplish this process in the very short windows indicated in the legislation. We appreciate that part of this work will be the need to crosswalk between standards used in the billing process today with the standards that support the HL7 Da Vinci PCT IG. For this reason, we are working closely with industry partners to support making such a crosswalk available.

**Insights on Additional Policy Questions**

The Departments also asked a number of questions about various policies related to this use case that have also been discussed within our Da Vinci community meetings on the PCT IG. The Departments ask about payers sending an AEOB back to the provider or facility that submitted a GFE, for instance. In our community discussions, this was noted as important and necessary. As such, the phase one Da Vinci PCT IG enables a payer to send the provider who submitted the GFE, a copy of the exact AEOB response sent to the patient. We do note that the IG does currently support sharing an endpoint to tie each provider, should there be co-providers, but this would require the convening provider knowing their endpoints, which could present another coordination burden for the convening provider. Ultimately, the IG could ease burden in helping to get the patient AEOB to care team members so that they are able to have informed discussions with the patient and they know exactly what information the patient has been provided, but at this time the HL7 Da Vinci PCT IG is primarily focused on the ability for the AEOB to be sent back to the GFE submitting provider due to existing real-world challenges related to provider-to-provider coordination discussed above.
Other policy questions the Departments raised in the RFI that we have discussed with the community or can assert the HL7 Da Vinci PCT IG supports include providing plain, accessible language and narrative descriptions in the AEOB and providing the diagnosis codes, which payers have noted is needed to produce an accurate AEOB. The IG can also support communicating consent to balance billing. We are working during our ongoing PCT IG ballot reconciliation process to add the ability to capture a “yes/no” flag indicating if a provider has or has not received consent from the patient to accept charges for non-covered providers or services. There are open questions about the timing requirements for when consent is needed and when the GFE must be submitted to the payer, but the IG can support communicating this information if available.

We look forward to the opportunity to continue to build and iterate on the HL7 Da Vinci PCT IG in support of the Departments and per future regulation. We believe that we will learn a great deal through early implementation and believe sharing our lessons learned could support iterating toward a less burdensome more valuable and actionable process for patients, providers, and payers. We are happy to further discuss any additional questions the Departments may have about the IG and/or accommodations needed to support future regulation. We believe strongly the HL7 Da Vinci PCT IG can help patients get the right data at the right time so they can use it to make informed decisions, and we are happy to help the community serve patients in this way.

Sincerely,

HL7 Da Vinci Project Steering Committee
cc: HL7 Da Vinci Project Membership

For more information on HL7 Da Vinci Project: https://confluence.hl7.org/display/DVP/Da+Vinci

HL7 Da Vinci PCT IG: https://build.fhir.org/ig/HL7/davinci-pct/

For a complete list of membership:
Steering Committee: https://confluence.hl7.org/display/DVP/Da+Vinci+Steering+Committee+Members

Operating Committee: https://confluence.hl7.org/display/DVP/Da+Vinci+Operating+Committee+Members