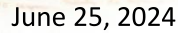

June 25, 2024

Michael Cimmino, Director
National Standards Group
Department of Health and Human Services
7500 Security Boulevard, Mail Stop DO-01-10
Baltimore, Maryland 21244-1850

RE: HIPAA Exception Report

Dear Director Cimmino,

Thank you for the opportunity to participate in the CMS exception to Health Insurance Portability and Accountability Act (HIPAA), which allowed members of the Health Level Seven® (HL7®) International Da Vinci Project (Da Vinci) to test new versions of standards to gain real-world data and experience to prove out the ability of the HL7 FHIR® standard for Prior Authorization (PA) to improve efficiency and further achieve administrative simplification as envisioned by the HIPAA regulations. As promised, the report on our findings is included.

As a private sector initiative, the Da Vinci Project is comprised of leading providers, payers and health information technology technical experts who are working together to accelerate the adoption of HL7 FHIR as the standard to support and integrate value-based care (VBC) data exchange across communities. With a focus on minimizing the development and deployment of one-off solutions, Da Vinci developed PA use cases and implementation guides that are freely available to all to address PA challenges, as standards-based strategies that are freely available to all have emerged as the way to address these pain points and improve care, reduce burden, streamline and automate workflow, liberate data and measure quality.

While the exception testing was limited to two participants – one payer [Regence BlueCross BlueShield of Oregon, a Cambia Health Solutions health plan (Cambia)] and one provider [MultiCare Connected Care (MultiCare)] - Da Vinci was able to demonstrate that the HL7 FHIR-based standards for PA significantly improved the PA process in comparison to the existing X12 278-based standard.

As we continue our interoperability efforts using HL7 FHIR, we welcome continued dialogue with CMS and industry as we are committed to collaboratively work toward transforming and improving healthcare for all, including feedback on how to reduce and remove barriers to participation in future testing and validation of new and emerging standards.

Sincerely,

Anna Taylor, MS CIPTC
Chair, HL7 Da Vinci Project Steering Committee
Assistant Vice President, Population Health & Value Based Care
MultiCare Connected Care

cc: HL7 Da Vinci Project Steering Committee; HL7 Da Vinci Project Operating Committee; Jocelyn Keegan, Program Manager, HL7 Da Vinci Project; Viet, Nguyen, MD, Technical Director, HL7 Da Vinci Project

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HIPAA Exception Report – June 2024

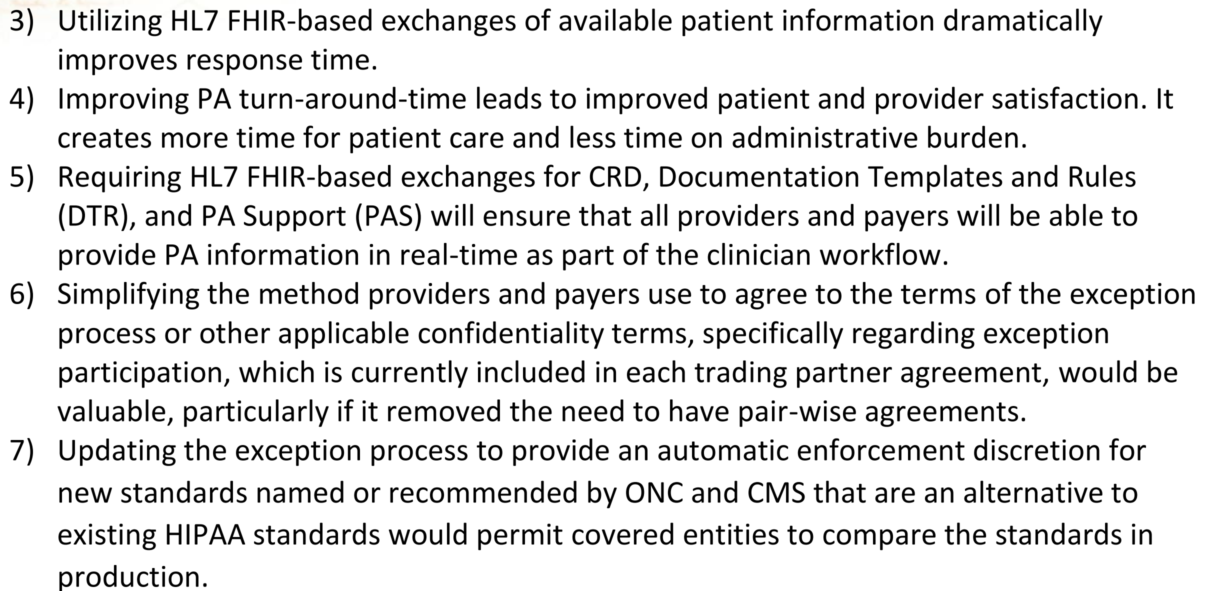
Executive Summary

While the exception testing was limited to two participants – one payer [Regence BlueCross BlueShield of Oregon, a Cambia Health Solutions health plan (Cambia)], and one provider [MultiCare Connected Care (MultiCare)] - the HL7® Da Vinci Project (Da Vinci) was able to demonstrate that the HL7 FHIR®-based standards for Prior Authorization (PA) significantly improved the PA process in comparison to the existing X12 278-based implementation. Key findings included:

1) An important aspect of the HL7 FHIR-based PA process implementation is an immediate response that indicates if a PA is required or not. The inquiries were for a benefits' check to see if services or treatments required PA. Eighty four percent (84%) of the time the services and treatments did not require PA, and providers received this answer in the Electronic Health Record (EHR) immediately. This immediate response allows for patient care to move forward, avoiding overhead to submit an entire PA with all the clinical requirements, and ensuring minimum necessary sharing of clinical data. This also decreases the number of PA submissions a payer has to process only to determine it is not required. Patients, providers, and payers all win with this automated and immediate benefit check.
2) In scenarios where PA was required for a service or treatment, MultiCare was able to view required clinical documentation and submit the PA directly from the EHR workflow. Cambia was able to quickly approve one-third of those submissions.
3) MultiCare reported significant improvements in the time it takes staff to submit authorization requests, moving from processing three to five PAs per hour to 10-12 PAs per hour without leaving the clinician workflow (a 140% to 233% improvement depending on PA complexity).
4) Cambia's technical implementation costs for the design, build, test, and deployment of FHIR APIs in support of all the solutions were approximately $135,000. Annual recurring costs are estimated to be approximately $200,000 inclusive of vendor licensing fees. MultiCare's technical implementation costs were limited to configuration of a SMART App within its Epic EMR system. These costs were less than $5,000.

Summary of Conclusions

1) Leveraging HL7 FHIR-based exchanges enables payers and providers to share an operational workflow. It improves the PA workflow and allows for direct integration into both payer operational and provider clinical workflows.
2) Using Coverage Requirements Discovery (CRD) to determine if PA is required based on the payer's policies and the specific patient conditions leads to a substantive reduction in PA submissions.



3) Utilizing HL7 FHIR-based exchanges of available patient information dramatically improves response time.
4) Improving PA turn-around-time leads to improved patient and provider satisfaction. It creates more time for patient care and less time on administrative burden.
5) Requiring HL7 FHIR-based exchanges for CRD, Documentation Templates and Rules (DTR), and PA Support (PAS) will ensure that all providers and payers will be able to provide PA information in real-time as part of the clinician workflow.
6) Simplifying the method providers and payers use to agree to the terms of the exception process or other applicable confidentiality terms, specifically regarding exception participation, which is currently included in each trading partner agreement, would be valuable, particularly if it removed the need to have pair-wise agreements.
7) Updating the exception process to provide an automatic enforcement discretion for new standards named or recommended by ONC and CMS that are an alternative to existing HIPAA standards would permit covered entities to compare the standards in production.

Organization of this document

1) Background
2) Testing Process for the Proposed Standard
3) Data Collection and Reporting Workflow
4) Test Results
5) Cost Benefit Analysis and Impact on Clinical Workflow
6) Conclusions
7) Appendix A – Definitions
8) Appendix B – Payer and Provider Side PA (not tested)
9) Appendix C – Goals and Justification for the Exception Request

Background

This Da Vinci pilot was established to evaluate the ability of HL7 FHIR-based standards to reduce the cost, complexity, and burden of Prior Authorization (PA). To do this, the National Standards Group (NSG) granted the following exceptions:

1) An exception from the use of X12 278 for a PA request and response when using the FHIR standards described in this request.

2) An exception from the use of the X12 270/271 when using CRD to determine if PA is required and performing Payer side PA (see Appendix B) based on the FHIR standards in this request.

In particular, a specific goal of this exception request was to assess the ability to integrate the PA process into the clinical workflow and provide results in real time. This will allow providers

to minimize the impact of PA on patient care relative to existing solutions, such as portals and telephone/faxing. The current process places a substantial burden on the provider, payer, and therefore the patient. In addition, the current process frequently causes a significant delay in necessary treatment. The pilot design was to evaluate the use of modern technologies, such as FHIR and RESTful exchanges, to support information transfer between providers and payers to:

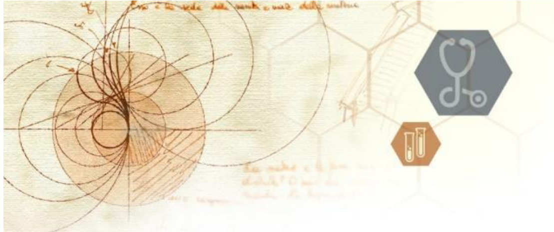
- determine the need for PA,
- collect the information necessary to support medical necessity and appropriateness,
- submit the request for PA within the clinical workflow, and
- receive a response to the request in real-time.

This was to be accomplished without requiring duplication of data entry and unnecessary delays in determining compliance with payer documentation requirements.

By utilizing three FHIR implementation guides (IGs), Cambia and MultiCare were able to, in partnership, demonstrate three significant improvements:

1) The ability to determine, in real-time, the need for PA using the HL7 FHIR Coverage Requirements Discovery (CRD) IG, and where appropriate grant the implied PA request.
2) The ability to collect and share clinical information necessary for PA by using the HL7 FHIR Documentation Templates and Rules (DTR) IG to execute payer documentation rules from an application that can retrieve required clinical information directly from the patient’s record when using the FHIR Questionnaire option (when required information does not exist, DTR questionnaires can request the provider or someone else in the practice to complete the necessary information prior to submission of the request to the payer).
3) The ability to submit the request for PA electronically using the HL7 FHIR PA Support (PAS) IG as opposed to converting it to an X12 278 or manually entering/exchanging information using a payer portal, fax, or telephone.

The Exception Request focused on the ability to determine if a PA is required by using CRD and exchanging the PA request and the response information between the provider and payer, using a FHIR Bundle as defined in the PAS IG, without converting it to and from the existing X12 278 standard. The associated clinical documentation, or attachments, were exchanged from the provider to the payer via the FHIR PA Request Bundle and do not require use of the X12 275 transaction typically associated with an X12 278 PA request when providing supplemental clinical data.



Note: additional goals and rationale for the exception request are covered in Appendix C: Goals and Justification for the Exception Request

The following two diagrams graphically depict the interplay between the three IGs that are part of the overall PA solution, and the exchanges between the provider and the health plan to submit the PA request and receive the final answer. Cambia's process requires human review of denials; that step is not illustrated in the graphics below but should be noted.

FHIR Prior Authorization Components

Provider | RESTful Exchange | Health Plan

(1) Provider orders or plans treatment

CDS Hooks request to payer

(2) Health Plan receives request and evaluates

(3a) Is PA required?

Yes

(3b) Coverage documentation rules / templates

No

(4) Response with documentation requirements if appropriate

Coverage Information via System Action

(5) Provider receives answer

If PA

(6) EHR / SMART App Retrieves the "Rules" and collects documentation of medical necessity (from patient record where possible)

CQL / Questionnaire

Coverage Requirements Discovery (CRD)

Documentation Templates and Rules (DTR)

Prior Authorization Support (PAS)

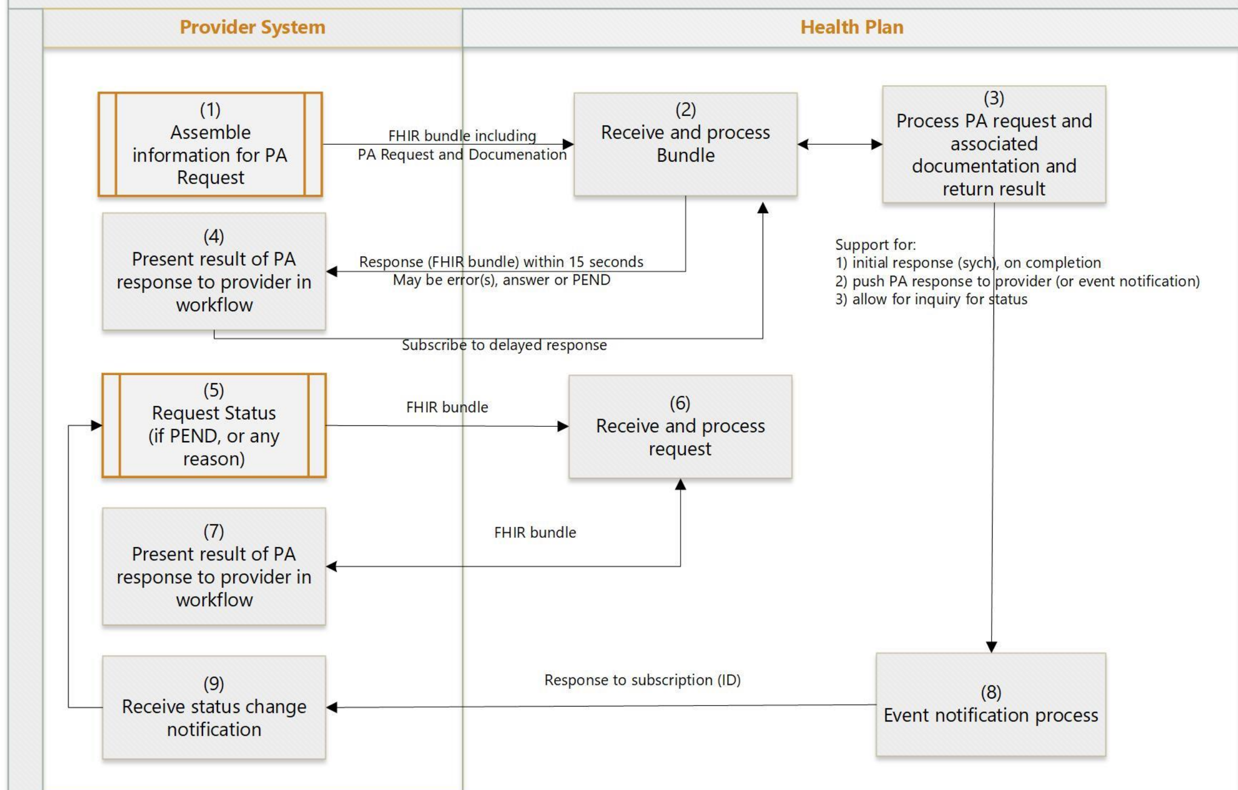
Submit PA Request

(7) Gathers all information for PA and supporting documentation and sends it to the health plan which returns an approval with a PA number, denial with reason or pending with reason

PA Request / Response

(8) Health Plan Receives PA request and attachments, process request and provides response

Note: if Pended, provider subscribes to PA request and retrieves response when status changes see Prior Authorization Support Workflow Graphic



Testing Process for the Proposed Standard

Based on the proposed Exception Request, the goals for this pilot testing included:

- Reducing the effort to identify services that require PA by a particular payer, within a particular plan.
- Reducing the effort to assemble documentation supporting medical necessity for a particular service and providing transparency of the medical policy requirements to clinicians and patients.
- Eliminating the need for the multiple proprietary payer portals that providers have to utilize to submit PA requests or eliminating the need for faxing or e-faxing clinical documentation.
- Improving patient care by reducing the substantial number of patients that do not follow-up with treatment recommendations if PA is not timely.
- Moving the workflow closer to the point of care by integrating the PA workflow with the EHR workflow.

Collection of data for reporting the results of the Exception pilot

The Exception Request was defined in such a way that it limited the data collection requirements to minimize the burden on providers.

The data collection to support evaluating the success of the pilot focused on:

1) Availability of the PA solution.
2) Response times from submission of a request to the payer until the initial response was given.
3) Time from submission to notification/receipt of a final answer.
4) Ability to exchange supporting clinical information.
5) Integration into the provider's clinical workflow and its impact on:
    a. Reducing duplicate entry.
    b. Reducing total provider/staff time spent obtaining a PA.
    c. Improving patient care by providing authorization and the ability to schedule appointments prior to the patient leaving the care setting.
6) Additional functionality tested as part of the exception process:
    a. Evaluating reduction in necessary clinical data shared with payer.
    b. Reduce denials for procedures in the pilot.

Participants

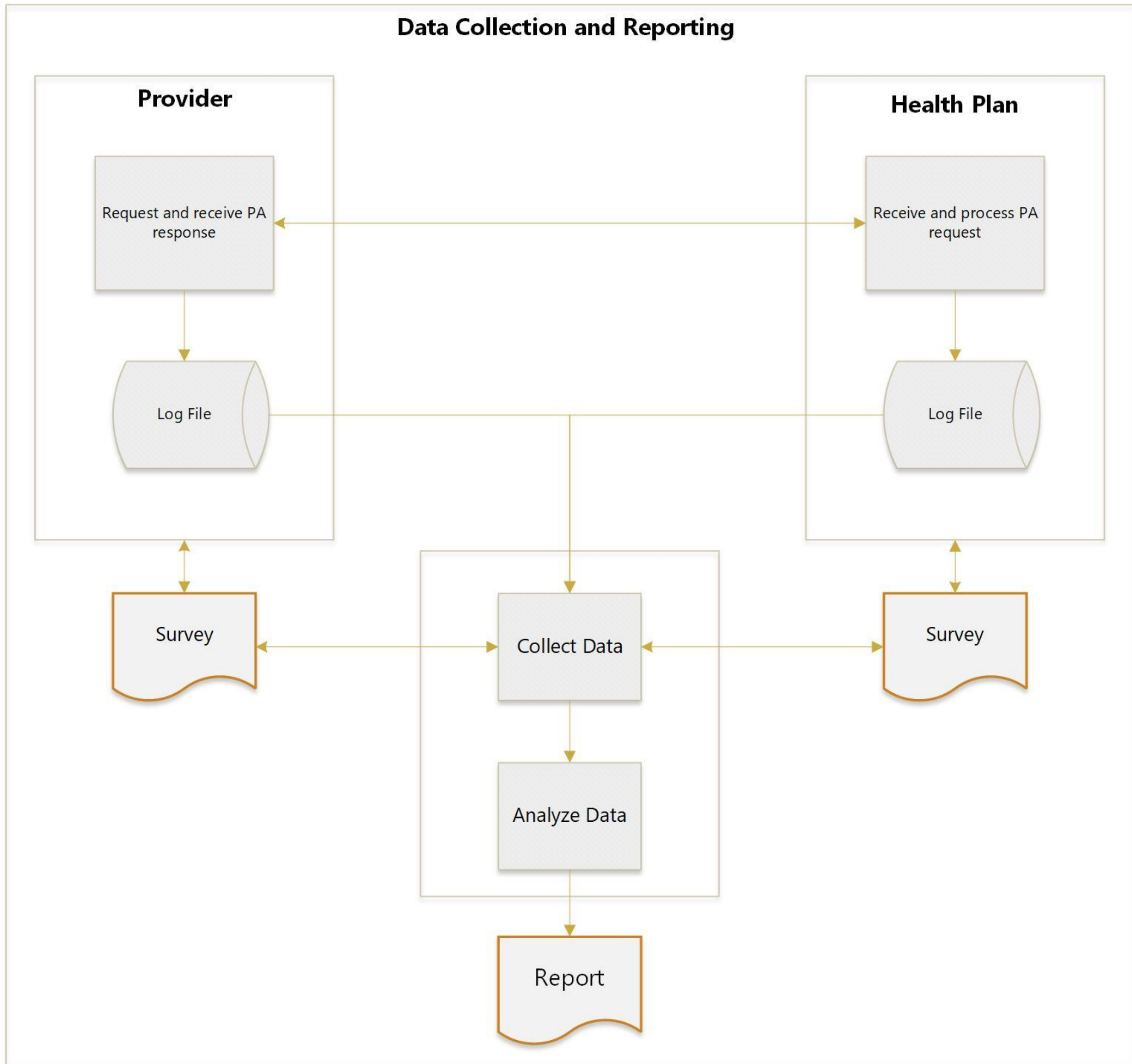
Due to the complexity of creating test environments and the need for formal trading partner agreements that included stringent testing and data reporting requirements, only one payer and one trading partner participated in the pilot. The two participants were:

- Payer: Regence BlueCross BlueShield of Oregon, a Cambia Health Solutions health plan (Cambia)
- Provider: MultiCare Connected Care (MultiCare)

Testing – Reporting

Da Vinci worked with Cambia and MultiCare to gather information from the production use of FHIR exchanges conformant to the CRD and PAS IGs.

Data Collection and Reporting Workflow



Test Results

Da Vinci and its members evaluated compliance with the CRD- and PAS-proposed standards by utilizing the AEGIS Touchstone platform. In addition, Da Vinci members and their participating trading partners accumulated statistics to determine the value delivered by the proposed standards in meaningful burden reduction and improvement of care.

Compliance with the technical standard

- AEGIS Touchstone automated testing tools were used to validate compliance of the implementation of PAS with the V1.0 of the published standards.

  Test Script Execution Information
  - /FHIRSandbox/DaVinci/FHIR4-0-1-PAS/PAS-2-0-1/01-PAS-Submit/dv-pas-01-claimsubmit-json-dynamic
  Exec Id: 20240403182712975215808
  Start Time: 04/03/2024 03:27:13PM
  End Time: 04/03/2024 03:27:31PM
  Status: Failed
  Duration: 18.809s
  Version:1
  Validator: HIR 4.0.1 Da Vinci (http://hl7.org/fhir/R4)
  Description:
  Da Vinci - PAS - FHIR R4 - 01 Claim Submit Dynamic - test to verify a client and server support for the Da Vinci PAS IG version 1.2.0 Claim $submitoperation using JSON syntax. If the Touchstone system is used as the Origin system, the Dynamic Fixture PAS Request Bundle entered for the TestScript atTest Execution will be used in the PA request. The test will validate both the request Bundle (Claim $submit) and the Claim response.
  Test Setup: FHIRSandbox--dv-pas-01-claimsubmit-json-dynamic
  Executed By: Ravi Kondiparthi (/touchstone/user?email=&userID=644c2f84f0f89c2ae89c9987)
  Organization: Cambia Health Solutions (/touchstone/org?id=5813e3be2953082c5b566f53)
  Origin: TouchstoneFHIR
  Destination: Cambia Health Solutions - Cambia PAS STU1 (/touchstone/testsys?id=660aeea46ee10f32b51e18f4)
  https://crd-uat.cambiahealth.com/v1/fhir

- The results of the testing indicated that additional work needs to be done on both the test scripts and the implementation to fully evaluate the implementation's conformance to the standard. However, since this implementation was based on PAS V1.0, there is no intent to adjust the testing tools, since the most recent version of PAS is V2.0 and should be considered the standard (including subsequent versions) for future implementations.

General availability and performance criteria

Cambia and MultiCare collected information to determine availability and performance for both the FHIR and X12-based exchanges.

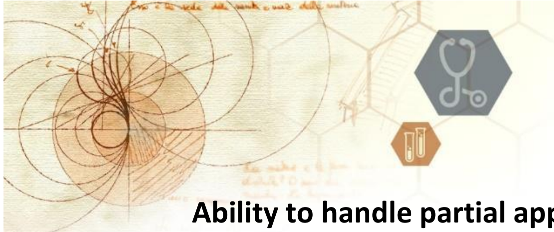
- **Availability**: Total availability of the FHIR-based APIs relative to the current X12 278 standard:

Standard	Availability of Service	Comments
Current Standard (X12 278 via a 3rd party Portal)	99.9%	Both solutions are designed for technical redundancy to minimize unplanned downtime and service interruption. Over the course of the testing period, ~10 hours of unplanned downtime occurred in web portal. Zero unplanned downtime occurred for the SMARTAuth FHIR API solution which is hosted by Cambia.
New Standard (FHIR APIs using SMARTAuth App)	100.0%	

- **Response time**: Overall measurement of the FHIR-based solution response time for the specific services or device requests. The goal was to have all responses returned to the provider in under 20 seconds from the time the request was submitted. This aligns with CAQH phase IV rules:

Standard	Response Time under 20 seconds	Comments
Current Standard (X12 278 via Portal)	98% for "PA Check" feature 95% for "Case Submit" feature	Both solutions are designed to deliver response times in under 20 seconds as per CAQH guidance. The portal feature for determining if a PA is required for a given service ("PA Check") responded within 20 seconds 98% of the time.[1] The portal feature supporting PA case submission where a PA is required ("Case Submit") responded within 20 seconds 95% of the time.[2] The FHIR API SMARTAuth solution feature for determining if a PA is required (CRD) responded within 20 seconds 99% of the time. The FHIR API SMARTAuth solution feature supporting PA case submission (PAS) responded within 20 seconds 95% of the time.
New Standard (FHIR APIs using SMARTAuth App)	99% for "Coverage Requirements Discovery (CRD)" 95% for "PA Support (PAS)"	

[1] Note: This is not a feature supported by the X12 standard. This is a custom feature created by Cambia and surfaced via a third-party portal.
[2] Note: This is not a feature supported by the X12 standard. This is a custom feature created by Cambia and surfaced via a different third-party portal.



Ability to handle partial approvals and denials

Measurement of completed responses (fully approved, denials) and partially approved as well as voided responses*.

Status	SmartAuth (FHIR)	Current 278 Portal
Fully Approved	71%	46%
Voided **	20%	45%
Denied***	8%	8%
Partially Approved	1%	1%

Notes:

***The findings are for one provider over a limited time and a limited data set for the SmartAuth FHIR solution.

****Voided transactions occur due to duplicate requests, cancelled requests, and data issues.

***** Cambia requires human review of all PA requests that cannot be approved electronically; values represent denials after completion of human review.

Ability to indicate that PA is not required

In addition to the metrics provided below, Cambia and MultiCare were able to validate the ability of the FHIR-based solutions to determine that PA was not required and thereby eliminated the delays and overhead of submitting a PA request when the service did not require a PA for that specific benefit. Specifically, they reported:

Standard	% PA Not Required	Comments
Portal Solution (X12 278 via 3rd party Portal)	77%[1]	For any specific service or procedure, the question of whether a PA is required is driven by a payer's medical policy. Therefore, the channel by which the request comes in (e.g., via FHIR API, portals submission, fax request, phone call, etc.) should not have a material impact on this metric. In other words, we should expect these percentages to be similar. However, when combined with the significant difference in "provider burden" associated with these two channels, these high percentages demonstrate the value of open standard FHIR APIs in the PA process. In the Portal solution, providers must leave their EHR workflow system and manually authenticate and interact with multiple payer portals to
FHIR Solution (FHIR APIs using SMARTAuth App)	83%	

		interface with payer processes like PA (aka "Payer Portal-itis"), as well as manage methodologies such as e-fax. In contrast, using FHIR APIs providers can use their native EHR system as their single "digital front door" to payers. This not only simplifies the process for back-office provider staff, but it also allows clinicians to understand whether a PA is required in real-time patient care.

[1]Note: This is not a feature supported by the X12 standard. This is a custom feature created by Cambia and surfaced via the third-party portal.

Ability to provide a timely response

- **Pended requests**: Measurement of completed responses versus pending requests to compare the proposed standard with the existing standard.
    i. Frequency of pending responses versus specific services
    ii. Comparison against existing solution standard for frequency of pending versus answers in real time
    iii. Average time to completion for all requests for a service in comparison against existing standards

Note: Cambia and MultiCare were able to track and measure the following metrics with their FHIR implementation that was compliant with the V1.0 of CRD and PAS.

Summary of metrics by service

Specific Service **(sample size > 15)**	**% Auto Approval – FHIR Solution** **(SMARTAuth + SMART App)**	**% Auto-Approval – Portals Solution** **(3rd party portal)**	**Comments**
Endometrial Ablation	85%	47% [1]	"% Auto-Approval" measures the percentage of time that a PA request received by Cambia was able to be approved without human clinical review. Note: PA denials are never done automatically; Cambia requires human review of denials. PA requests typically require supporting clinical data submitted by the provider to the payer. Submission of discrete data helps improve confidence in enabling auto approvals. In a portal-based solution, these discrete data submissions are not supported by the X12 278[1,2] and must always be done manually. A FHIR API solution allows for the capability to pull data directly from provider systems, increasing the likelihood that the required data is correctly submitted. However, this advantage is necessarily limited to the extent that the data required for the PA approval is available within the provider's system.
IMRT Thorax, Abdomen, Pelvis, Etc.	28%	50% [1]	

			For example, in pilots with Cambia and MultiCare, the scope of the FHIR solution used was limited to MultiCare's Epic EHR system. For those specific services (e.g. Endometrial Ablation) where the required supporting data was stored in MultiCare's Epic system, the pilot results demonstrate the advantages of FHIR solutions for obtaining the right clinical data the first time for a determination. For other services (e.g., IMRT Thorax, Abdomen, Pelvis, etc.), certain required supporting data was stored in MultiCare's oncology system, which was out of scope of the pilot[2]. While the SMARTAuth application allows the provider to upload additional data manually, MultiCare staff using the SMARTAuth solution were not instructed to use that feature to upload data from the oncology system.

[1] Note: This is not a feature supported by the X12 standard. This is a custom feature created by Cambia and surfaced via the third-party portal.
[2] See more oncology focused progress: "HL7s Accelerator Codex Launches Pilot to Simplify Prior Authorizations in Oncology"

Specific Service (sample size > 15)	**Total PA Processing Time (rounded to nearest min/hour/day)**				**Comments**
	Top 25%	Top 50%	Top 75%	Top 90%	When PA requests are not able to be auto-approved (more complex criteria), they require human review. These metrics demonstrate the reduction in time and effort on the part of the payer even in cases where human review is required. This benefit can be attributed to the capability of codified medical policies that can access required data inside the EHR (see Endometrial Ablation above). For specific services where required data is stored in a system that is out of scope of the FHIR Solution (see IMRT Thorax, Abdomen, Pelvis above) the benefits are not fully realized.
Endometrial Ablation					
Portal Solution	97 min	4 days	5 days	8 days	
FHIR Solution	1 min	1 min	5 min	7 days	
IMRT Thorax, Abdomen, Pelvis, Etc.					
Portal Solution	1 min	1 day	14 days	49 days	
FHIR Solution	1 day	1 day	8 days	11 days	

Flexibility of proposed standard

Criteria

1) Ability of the proposed standard to support new services, additional criteria for existing services, or changing criteria for existing services.
2) Ability of the proposed standard to exchange clinical documentation required to show medical necessity of appropriateness.

According to Cambia:

The payer has full flexibility to change or update the criteria at any time deemed necessary. The payer has a tool available to add new policies or update existing policy criteria for full visibility to the provider within the workflow.

According to MultiCare:

The provider has full flexibility on where PA workflows are evoked in the clinician workflow. This could be a centralized or decentralized model of PA submission. It also enables discrete data sharing without the need for attachments. In addition, this enables providers the ability to display PA results in patient portals (e.g., just as you would see a lab result in your patient portal, you could see a PA result).

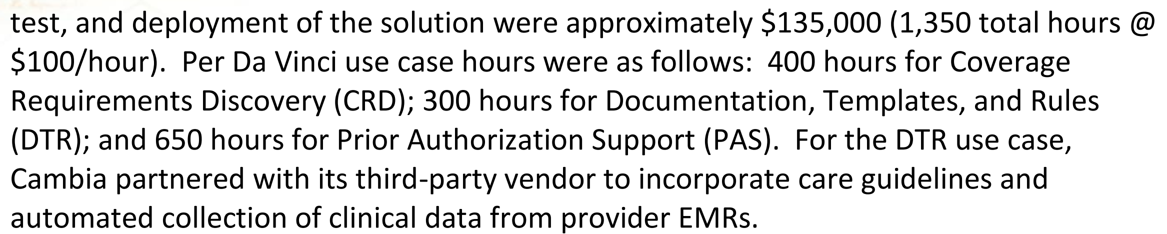
Cost Benefit Analysis and Impact on Clinical Workflow

The cost benefit analysis is focused on the emerging use of FHIR to promote real-time solutions for the exchange of important clinical and administrative information.

- Both ONC and CMS require FHIR to solve previously intractable interoperability problems. While we have not directly compared the cost of implementing the X12 278 transactions, we will note that the X12 278 standard is not designed for easy implementation in a real-time clinical workflow. We do note that CRD, DTR, and PAS are all FHIR-based APIs called out in current regulations, specifically the CMS Interoperability and Prior Authorization final rule. These APIs also build on the FHIR requirements specified in the 21st Century Cures Act final rule and ONC's subsequent HTI-1 final rule. By building on the current FHIR requirements, the effort/cost to implement the PA IGs is substantially reduced.

- In addition to leveraging existing FHIR API capabilities including those implemented for previous CMS mandates, Cambia's technical solution took advantage of existing capabilities previously developed in support of legacy (e.g. web portal and faxed submissions) prior authorization processing.

- Cambia's FHIR API solution was developed by internal staff on cloud infrastructure using open-source components and libraries. Cambia development costs for design, build,



test, and deployment of the solution were approximately $135,000 (1,350 total hours @ $100/hour). Per Da Vinci use case hours were as follows: 400 hours for Coverage Requirements Discovery (CRD); 300 hours for Documentation, Templates, and Rules (DTR); and 650 hours for Prior Authorization Support (PAS). For the DTR use case, Cambia partnered with its third-party vendor to incorporate care guidelines and automated collection of clinical data from provider EMRs.

- Cambia's total recurring annual support costs are estimated to be less than $200,000 annually.
- MultiCare's technical implementation costs were limited to installation of a Cambia-developed SMART on FHIR App ("SMARTAuth") to support provider-side workflow and user experience. The SMARTAuth app was made available in the Epic App Orchard and was implemented and configured by MultiCare technology staff to augment the native capabilities of MultiCare's Epic EMR system. Estimated implementation costs of the SMARTAuth app for MultiCare were less than $5,000 and including the following: 22 hours for SMARTAuth install and configuration; 8 hours for SMARTAuth testing and validation; 4 hours for staff training.
- As part of the benefit analysis, this exception evaluation process clearly demonstrates a significant number of benefits that are not possible when using the HIPAA-required X12 278 transactions.
    1) The ability to integrate directly into the clinical workflow substantially reduced the burden on the practice and the patients by providing an immediate response that indicates if a PA is required or not. This immediate response from CRD was directly responsible for reducing the actual prior authorizations submitted to the payer by eighty four percent (84%). By allowing patient care to move forward, both providers and patients benefited from the ability to immediately plan the next phase of the patient's care.
    2) In scenarios where PA was required for a service or treatment, the provider could view required clinical documentation and submit the PA and supporting documentation directly from the EHR workflow. Since the required documentation was included with the PA request, the payer quickly approved one-third of those submissions.
    3) Providers reported significant improvements in the time it takes staff to submit authorization requests, moving from processing three to five PAs per hour to 10-12 PAs per hour without leaving the clinician workflow (a 140% to 233% improvement depending on PA complexity).

Conclusions

FHIR-based exchanges, unlike X12-based exchanges, enable provider EHRs, including supporting HIT modules, to easily integrate benefit checks and PA exchanges with payers directly into clinical workflows. By using CRD, the provider is immediately aware of the payer's requirement for PA for a specific ordered service or treatment based on the coverage rules for the patient's/member's plan. Since the fully automated exchanges are with the responsible payer, there is no need to assemble documentation and request PA

approval when it is not required. Based on the exception test results, up to 84% of services that otherwise may have resulted in unnecessary PA request were verified as not requiring a PA and therefore eliminated overhead and delays associated with unnecessary PA requests.

For services that required PA, the application (DTR-based) was able to assist in the assembly of documentation required by the payer's plan to show medical necessity and appropriateness and resulted in real-time approval for one third of the PA submissions. This allowed providers to immediately arrange for the next step in the patient care journey. In addition, it substantially reduced the time required to prepare and submit a PA request to the payer, resulting in a 140% to 233% improvement in PAs submitted per hour. An additional benefit is eliminating the need to support a separate "attachments" transaction for documentation submission.

Since the payer's requirements for PA approval for the specific service are exchanged via a standards-based RESTful FHIR transaction, it enables the provider to have a consistent clinical workflow uninterrupted by non-standard payer implementation (e.g., portals). By having a standards-based exchange, all payers present their requirements for PA and the supporting documentation using the FHIR-based representations in the same underlying manner. This improved PA workflow allows for direct integration into both payer operational and provider clinical workflows.

In conclusion, this exception resulted in demonstrating substantial benefits in using the FHIR-based real-time transaction over the existing X12 278. The benefits include:

1) Using CRD to determine if PA is required based on the payer's policies and the specific patient conditions leads to a substantial reduction in PA submissions.
2) Automating the assembly and exchange of available patient information dramatically improves PA decision response time.
3) Increasing the speed of PA determinations leads to improved patient and provider satisfaction.
4) Implementing more efficient PA processes creates more time for patient care and less time on administrative burden.

Requiring FHIR-based exchanges for Coverage Requirements Discovery (CRD), Documentation Templates and Rules (DTR), and PA Support (PAS) will ensure that all providers and payers will be able to provide PA information in real-time as part of clinician workflow.

The participants in this exception observed two significant issues that were barriers to broader participation and should be addressed as part of any future exception grants.

1) The exception process needs a more simplified method for providers and payers to agree to the terms, regarding the Exception requirements, currently it requires inclusion of trading partner agreements. This new process should enable a provider or payer to declare conformance with the exception's requirements and be permitted to work directly with any other compliant partner. This could reduce the administrative burden of legal review and trading

partner agreement execution, between all provider-payer pairs. This could be implemented by having the sponsoring group (e.g., Da Vinci) provide a cost-free method for provider groups to join. Then, the exception could be issued to, for example, all Da Vinci Payer and Provider Groups.

2) An alternative is to have the exception process provide an automatic enforcement discretion for new standards named or recommended by ONC and CMS that are an alternative to existing HIPAA standards. This will permit covered entities to compare the standards in production. By allowing providers and payers that are implementing new standards to use those standards in production without concern for enforcement, will significantly reduce the barrier to participation. The result of the evaluation of new standards will provide evidence that the old and new standards should continue to be supported in parallel, or the new standard should replace the old standards as soon as is practical.

Da Vinci, Cambia Health Solutions, and MultiCare Connected Care wish to thank the National Standards Group for their support in this opportunity to evaluate FHIR-based PA exchanges in a production setting, which in turn supports our shared investment into highest level of care we are able to provide our members, patients, and communities we serve, paving the way to healthier futures.

Appendix A

Definitions

Term	Definition
CRD	HL7 FHIR Da Vinci - Coverage Requirements Discovery (CRD) Implementation Guide http://hl7.org/fhir/us/davinci-crd/STU1/
DTR	HL7 FHIR Da Vinci - Documentation Templates and Rules (DTR) Implementation Guide http://hl7.org/fhir/us/davinci-dtr/STU1/
HL7 FHIR[T]	References the use of Release 4 (R4) of the FHIR standard and any relevant future releases.
NSG	National Standards Group
PA	Prior Authorization; also Request for Review and Response
PAN	PA Number
PHI	Protected Health Information
PAS	HL7 FHIR Da Vinci - PA Support (PAS) Implementation Guide http://hl7.org/fhir/us/davinci-pas/STU1/
Service	Any healthcare service, device [e.g. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)], referral, admission, therapy that may be subject to PA.
X12 270/271	The Accredited Standards Committee X12 (ASC X12) Standards for Electronic Data Interchange Technical Report Type 3—Healthcare Eligibility Benefit Inquiry and Response (270/271), April 2008, ASC X12N/005010X279, as referenced in §162.1202.
X12 275	The ASC X12N 275 6020 TR3 Additional Information to Support a Healthcare Services Review (or any version named into regulation).
X12 278	The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Healthcare Services Review—Request for Review and Response (278), May 2006, ASC X12N/ 005010X217, and Errata to Healthcare Services Review—Request for Review and Response (278), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, ASC X12N/005010X217E1, as referenced in §162.1302.

Appendix B

Payer and Provider Side PA (not tested)

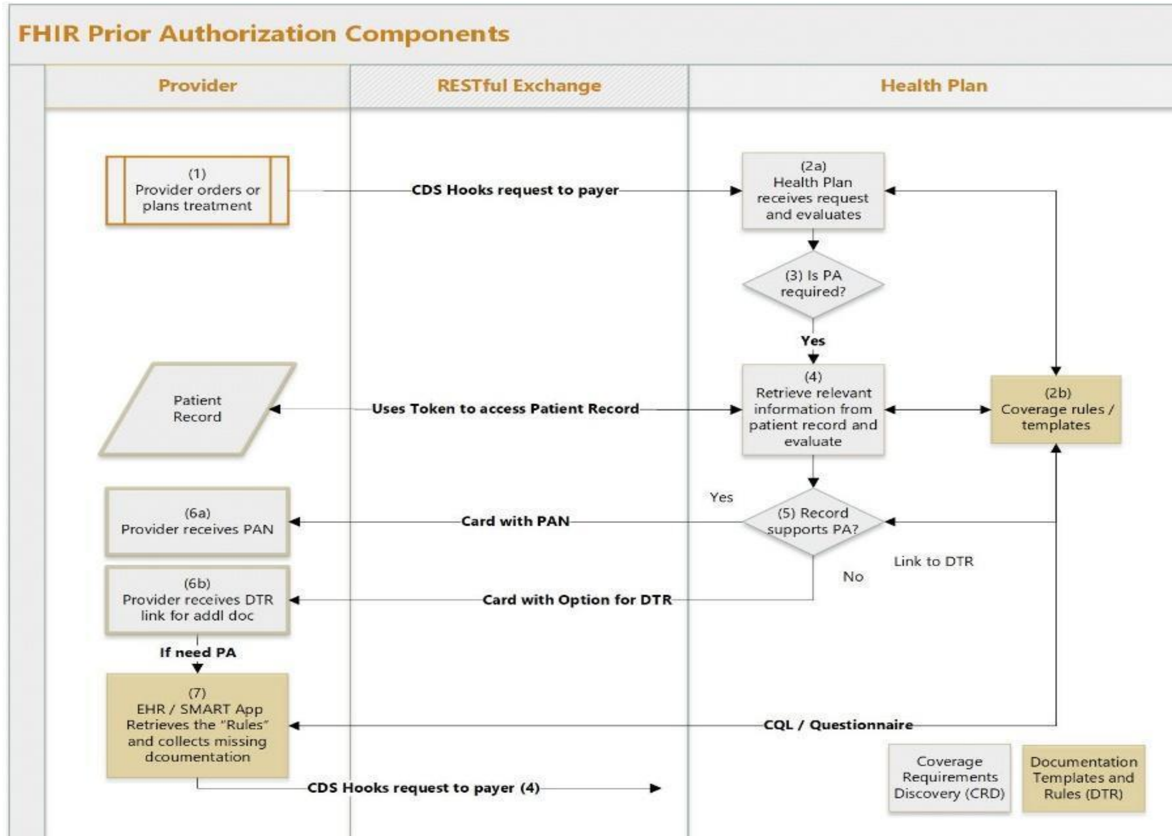
The alternate approaches to integrating PA into clinical workflow described below were submitted as part of the Exception Request and were not evaluated during the Exception Period.

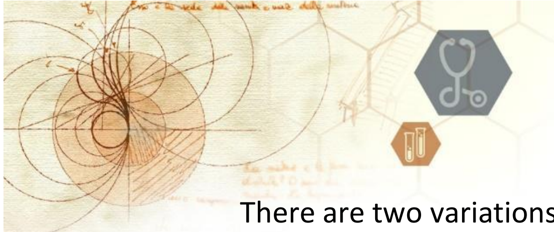
Payer side PA

After further consideration during the pilot efforts, we believe that Payer side PA has significant benefit in providing simplified PA without needing to manage the complexities of formally submitting a PA request via PAS when the information necessary to evaluate and approve the PA is available in the CRD and DTR interactions.

Background

CRD is used to determine if a PA is needed for a specific service. If PA is required, the payer uses the provider supplied access token to access the patient's record to determine if it contains all of the information required to support the medical necessity of the indicated service. If there is sufficient information to determine that the service is appropriate to authorize, the payer returns a result (authorized, denied, requires additional information), along with the PA number (PAN) if appropriate.





There are two variations of the Payer side PA:

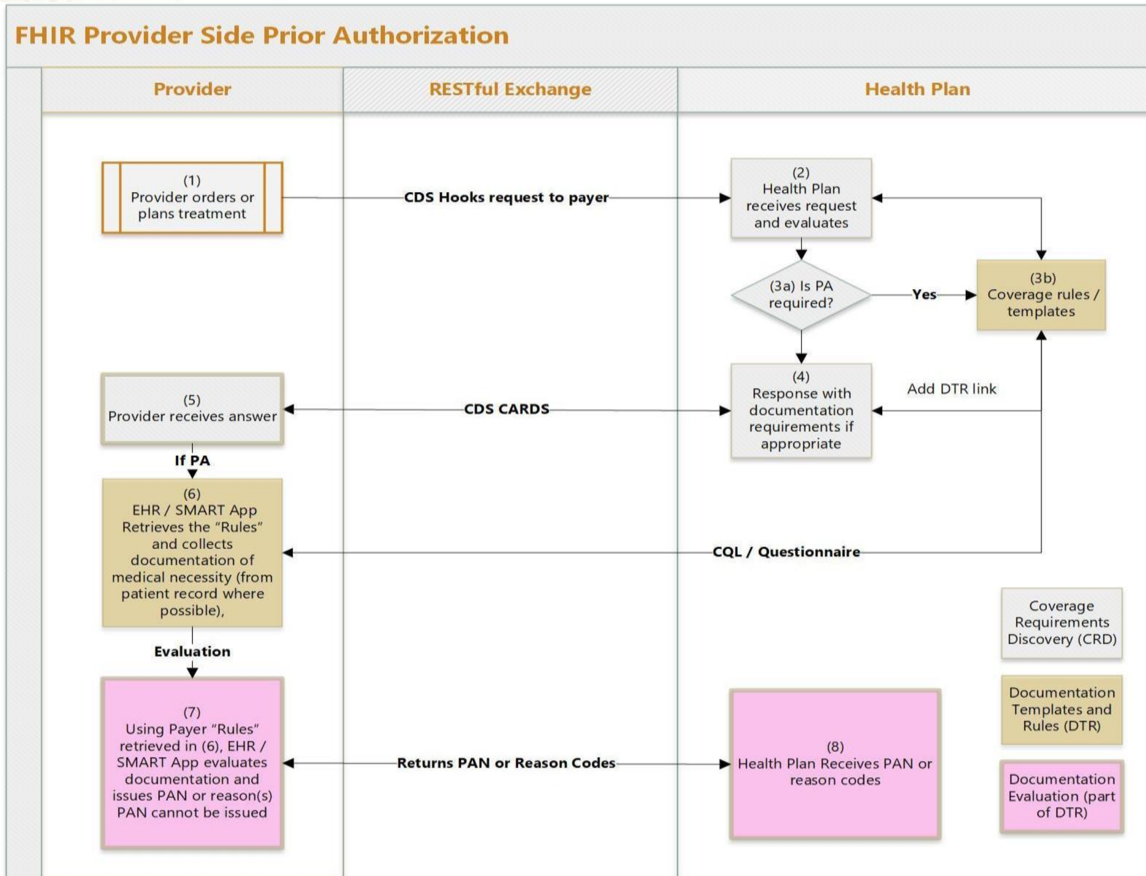
1) The first assumes that all clinical data necessary for PA is already in the patient's record and the determination will be made without additional intervention on the part of the provider. The resulting card returned by CRD will provide the PAN or the denial reason.
2) The second variation occurs if the information in the patient's record is insufficient to determine medical necessity. In this case, the returned card will indicate that additional information is required and provide the ability to start a DTR-compliant process. The DTR-compliant process will gather the missing information only and return it to both the patient's medical record and the payer to complete the authorization process. Once the additional information is received, the process will provide the provider with the PAN or the denial reason.

Provider side PA

After further consideration during the pilot efforts, we do not have any reason to believe at this time that Provider side PA is practical, since it 1) requires all of the payer's rules regarding a specific service to be encoded and sent to the provider's EHR or a SMART app for execution and 2) does not permit the use of complex payer information in making the determination of medical necessity and appropriateness.

Background

Da Vinci also proposed testing a provider side authorization. In this scenario, CRD may be used to determine that a PA is required. A DTR compliant process will access rules from the payer regarding both the information required to demonstrate medical necessity as well as rules required to evaluate that information and determine if authorization can be provided. Those rules will: 1) evaluate the relevant portion of the patient's record and 2) request additional documentation from the provider in the event that the record does not contain the necessary information in a computable format. If the information is still incomplete, it may be necessary for this process to use a Provider-Payer request for authorization along with the exchange of associated clinical information. In this case, a FHIR bundle is exchanged as part of the exception without converting it into and out of the ASC X12 275.



In the event the authorization can be granted, the application will generate the PAN within the context of the EHR and no clinical data will be exchanged with the payer. In the provider side authorization, the only exchange will be a message going back to the payer indicating that authorization has been approved, denied, or deferred. In the event it has been approved, the associated PAN generated by the application will be returned to the payer for inclusion in the billing system.

Appendix C

Goals and Justification for the Exception Request

Goals of the proposed standards (excerpted from the Exception Request and updated as appropriate)

I. Improve the efficiency and effectiveness of the healthcare system by leading to cost reductions for, or improvements in benefits from, electronic healthcare transactions

The proposed FHIR-based standard for PA will provide the following potential benefits to improve the efficiency and effectiveness of the healthcare system:

- Reduce the effort to identify services that require PA by a particular payer,
- Reduce the effort to assemble documentation supporting medical necessity for a particular service,
- Eliminate duplicate entries currently required by payer portals, and
- Improve patient care by reducing the substantial number of patients that do not follow-up with treatment recommendations if PA is not received in a timely manner.

II. Meet the needs of the health data standards user community, particularly healthcare providers, health plans, and healthcare clearinghouses

To meet the needs of the health data standards user community, we are proposing to use a set of new standards based on HL7 FHIR. The HL7 FHIR standards have been broadly adopted by healthcare providers primarily through their EHR technologies to exchange clinical information using standard APIs.

This technology has also been cited for adoption by ONC as part of their final rules. CMS has also required the use of HL7 FHIR APIs to exchange information and promote interoperability in both of their recent interoperability rules.

By using the same standard that is being promoted in both ONC and CMS final rules, this pilot has tested standards based on technologies that are the future for interoperability as determined by the provider and payer communities.

It is unclear at this point exactly what role clearinghouses will play in the exchanges using HL7 FHIR. However, it is assumed that intermediaries, whether they are clearinghouses or other entities, will play a role in scaling access to and support for FHIR transactions. A significant part of this scaling work is being done through the HL7 *FAST* project, which has promoted scaling solutions utilizing intermediaries to address issues related to authorization authentication, message routing, and value-added services.

III. Be uniform and consistent with the other standards adopted under this part and, as appropriate, with other private and public sector health data standards.

By utilizing HL7 FHIR as the standard for addressing the PA needs of the healthcare sector and providing the ability to translate the FHIR standard to the existing ASC X12 278 standard, where appropriate, the industry can continue to use the existing ASC X12 infrastructure where it is currently available and adequate.

The proposed FHIR standards ensure both evolving support for existing exchanges using the ASC X12 278 and provide for the evolution to a FHIR only standard where appropriate.

IV. Have low additional development and implementation costs relative to the benefits of using the standard.

The proposed HL7 FHIR-based standard has an extremely low development and implementation cost relative to the benefits of adopting the proposed standard. The development community for HL7 FHIR-based solutions for healthcare is an order of magnitude larger than the standards effort focused on extending support for the ASC X12 278 standard. In fact, it is highly unlikely that the subsequent versions of the X12 278 standard will actually solve the PA problems due to the lack of integration into the clinical workflow. The ability to take advantage of APIs that have been developed to meet clinical interoperability to automatically retrieve and exchange supporting documentation provides a substantial benefit and significantly reduces the time and effort to extend the capability of the proposed standard. We anticipate that as API capability evolves for providers and payers, we will see convergence of both administrative and clinical data in a way that will significantly benefit value-based care. The proposed solution is based on a standard that is utilizing current internet-based technologies (JSON, REST, etc.) to meet the evolving needs of healthcare services. This is unlike the existing standard which was developed several decades ago and has not evolved in its ability to integrate into clinical workflow or represent clinical information.

V. Be supported by an ANSI accredited SDO or other private or public organization that would maintain the standard over time.

The proposed standards (implementation guides) were developed as part of HL7 International's ANSI accredited open standards process. These guides will continue to be maintained by members of HL7 International community, including but not limited to the members of the Da Vinci project. It is the intent of the supporters of these guides that they will continue to evolve based on experience during implementation and result in the normative standard specification compliant with HL7 documented standards process and requirements.

VI. Be technologically independent of the computer platforms and transmission protocols used in electronic health transactions unless they are explicitly part of the standard.

The technology for the implementation guides that are part of this exception request are based on the HL7 FHIR standard. The standard is platform independent and transmission independent. It is focused on the representation and exchange of information related to healthcare. Unlike other standards, which tried to solve broad industry problems for which healthcare is only one sector, HL7 FHIR is focused solely on supporting information representation exchange associated with the healthcare sector and its services. The ability to focus specifically on healthcare allows the standard to precisely represent healthcare related information in a way that is impossible for a more broadly based standard.

While HL7 FHIR is transmission independent, the guides constrain the exchange to use RESTful Web services. The PAS guide specifies exchange with an operation endpoint that provides a defined set of services. These services include the ability to:

- Receive a FHIR transaction bundle
- Respond to that transaction bundle within a defined period of time
- Allow for the ability to track the status of an incomplete PA
- Alert the submitter when a change has been made in the request
- Query the status of the PA
- Update the PA request
- Cancel the PA request

This capability is provided for both the ordering and performing provider where appropriate.

VII. Incorporate flexibility to adapt more easily to changes in the healthcare infrastructure (such as new services, organizations, and provider types) and information technology.

By using HL7 FHIR the proposed solution adapts more easily to changes in healthcare infrastructure. It can easily support new services, new organization types, new provider types, and respond to changes in information technology infrastructure.

By incorporating the ability to exchange both the request for PA and the associated documentation of medical necessity in a single fire bundle, the solution provides the ability to address real-time review of clinical documentation using FHIR resources with structured and coded data allowing for automation of the review process. Expanding the scope of services, organizations and provider types is accomplished by expanding CRD responses and DTR rules. The ability of PAS to communicate the resulting information for review by the payer will accommodate currently anticipated changes.