SYSTEMS TECHNICAL ADVISORY GROUP
INTEROPERABILITY WORKGROUP: **QUESTIONS FOR CMS**

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- Identify areas needing additional information and guidance from CMS and/or ONC
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- Propose implementation resources to assist all States

PATIENT ACCESS API

Beneficiary Identity Verification and Authorization

1. Can we require the participant to go to our web portal for identity verification and assignment of a user name and password before they access their data using the third party app and require the participant to enter the credentials when accessing the data?

CMS Response: *this question is under review by CMS.*
Context: *In general the process should enable the individual to provide information to the 3rd party app; this information will shared with the payers to ensure the right information is going to the right person. The issue facing some State Medicaid agencies is that Medicaid beneficiaries do not have Medicaid "accounts" or existing information that would allow for identity validation and verification.*

For Medicare's Blue Button initiative, beneficiaries who did not have existing mymedicare.gov accounts, established such accounts through the apps.

Beneficiary Questions and Support

2. Can we require the beneficiary to first contact the third-party developer for support when the participant has issues accessing our data through the third-party app?

CMS Response: *Yes; the expectation is that the individual will go to the app for assistance. In addition, the payer needs to provide educational materials that will support individuals in the use of 3rd party apps. These materials should remind individuals to go to the app for help.*

Data that Must be made Available:

3. Clarification on SHO #20-003
   Pg. 3: States may be best able to compile all data elements described for the Patient Access API in 42 CFR 431.60 through connections to health information exchanges or public health agencies, or human services agencies. Specifically, the required data in the United States Core Data for Interoperability (USCDI) described at 45 CFR 170.213 might include information residing in health information exchanges or public health agencies (for immunization data, lab test and result data, etc.), or human service agencies, and states should review if establishing such connections would be appropriate.
   and

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42 CFR 431.60 requires the following data to be made available:

(1) Data concerning adjudicated claims,
(2) Encounter data
(3) Clinical data, including laboratory results, if the State maintains any such data,
(4) Information about covered outpatient drugs and updates to such information

Clarification Requested: Which of the above data elements would be available through connections to health information exchanges, public health agencies, or human service agencies? Is this paragraph placing another requirement on the State Medicaid agency? In other words, if lab results or immunizations are not currently maintained by the State Medicaid agency, does the final rule require the State Medicaid agency to connect to a public health agency to make that information available via the API? While State Medicaid agencies can appreciate the benefits to accessing this information for the beneficiary, for many States it will require additional data exchanges.

CMS Response: *Any data that a payer maintains as part of an individual's records and that falls into one of these categories:*

- *-clinical data in the form of the USCDI;*
- *Claims and encounter data*
- *Formulary information*

Must be made available via the Patient Access API.
CMS defines "maintain" as data which you have access to, use of, and control over. This may be through a contractor, for example, a contract with a state health information exchange (HIE) for clinical data. Control means there is no existing law or data use agreement that would prohibit you from sharing the data. If you do not maintain the data, there is no expectation that you will need to provide access to it. General Rule: if the data could be shared today, it must be made available through the Patient Access API. The API should not change any of the existing policies around access to data.

4. Does the USCDI provide standards for Medicaid claims and encounter data, Non-emergency medical transportation, and LTSS?

CMS Response: *Claims and encounter data should follow the Carin BlueButton Implementation Guide (IG) http://build.fhir.org/ig/HL7/carin-bb/toc.html*

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Based on a CMS response provided during an HL7 seminar: the payer is in compliance if the payer follows the IG, even if the IG does not include specific services. For example, as of today (11/02/2020), the IG does not include dental nor vision services. If the implementation date were today, any payer following the IG, even though it does not recognize dental or vison services, would be compliant with the rule.

5. Will the claims and encounter data need to be transmitted in other languages?

CMS Response: *No specific requirements or prohibitions on any language; no expectation on translating data. Recommend that you consider the needs of your population.*

6. What are the boundaries of data that must be provided. For example, if the State maintains results of utilization review -this is data with a clinical content used for an admin purpose – is this expected to be made available?

CMS Response: *How do you currently maintain the data? Is it part of the individual's record? Can it be mapped to FHIR? If yes, then it should be shared.*

7. How is cost data defined?

CMS Response: *Refer to Carin BlueButton IG- the definition of cost is based on the cost reflected in an EOB.*

8. Please clarify the requirement that claims data from 1/1/2016 be available. Does this requirement stand forever or is CMS' intent to make data available on a rolling basis? So in 2022, data from 1/1/2017 on is available?

CMS Response: *The ultimate goal of the rule is to provide everyone with access to their lifetime of health data. The requirement to provide an individual's data dating back to 01/01/2016 remains as long as the individual is enrolled with the payer. If the individual requests data in 2035, it needs to be provided from 1/1/2016.*

Note that this applies to current enrollees only. Current policies around enrollment should guide how a State Medicaid agency defines currently enrolled/eligible. For example, an individual loses Medicaid eligibility and then re-applies a few months later. If the State views the individual as a brand new eligible and does not associate the person with their previous case, then the prior period of eligibility does not apply and the data from that earlier period would not be available. If the State, re-connects

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the new eligibility period with the former period, then the previous data should be made available.

Note that rules for payer-to-payer data exchange, currently not applicable to State Medicaid FFS, are different.

CMS did not include this example, but it may be helpful. A Medicaid eligible individual is eligible on 01/01/16. The person begins a period of incarceration on 01/01/2018. The incarceration results in suspended (but not terminated) eligibility. The individual is released on 01/01/2019 and continues to be Medicaid-eligible. The individual should be able to access their data from 01/01/2016.

CMS did clarify that for current patients, you must maintain the data as of 1/1/2016- regardless of existing record retention policies.

Data Release

9. It would be helpful to have more clarification regarding the sharing of sensitive data where federal or state law requires a higher level of consent than HIPAA.

10. Do we have the option to not make data for vulnerable populations available through the API? An example would be foster children in state custody where State case workers would access the claims data for these kids through an existing web portal.

CMS Response to #9 and #10: *All existing laws related to data-sharing stand. For example, if consent exists to share Part 2 data, then that data can be accessed via the API. If no such consent is on file, then that data may not be shared. Any existing privacy policies need to be maintained.*

Review of Third Party Apps

11. When the final rule states that the States can deny access to a third party app for security reasons, how did CMS envision that the states would identify the security issue before receiving a request to release PHI?

CMS Response: *The rule allows payers to require 3rd party app developers to attest to maintaining specific security protocols and payers need to educate beneficiaries. CMS has issued guidance here: https://www.cms.gov/files/document/patient-privacy-and-security-resources.pdf*

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Additional resources noted were the CARIN Alliance Code of Conduct: https://www.carinalliance.com/our-work/trust-framework-and-code-of-conduct/

Third Party App Developers: Use of Data

12. Will third party applications be able to sell the data received through a State's or MCO/PIHP/PAHP's API?

13. Will the ONC or CMS certify third party applications?
    CMS Response: *CMSis not establishing certification program for 3rd party apps.. CMS does not believe current authority provides the ability to require a third-party app to take part in such a certification program.(pg. 40 Final Rule)*

    Payers can request that 3rd party apps attest to certain security requirements.

14. Does the implementation of the APIs have any safe harbor provisions to limit any liability that State Medicaid agencies face?

Resources

15. Has CMS approved/endorsed the Carin Alliance voluntary app developer registration and credentialing project (presented on a recent State Health IT Connect webinar)?

Funding

16. If the State requested enhanced funding via the APD will there be CMS certification required to qualify for Maintenance & Operations enhanced match? If yes, what would this look like (e.g., outcomes-based, MECT 2.3)?

CMS Oversight

17. Will there be sanctions/penalties for late or noncompliance?

18. Federal regulations (45 CFR Parts 75 and 95) require states to engage in open, competitive procurements to the maximum extent practical. The final rule has a very aggressive timeline compounded by protracted State procurement processes that make open competitive procurement difficult to do (within the July 2021 timeframe). Will CMS give some leeway when States seek prior approval for a sole source/non-competitive procurement?

19. Will there be an opportunity to seek Good Faith Effort relief similar to the EVV mandate?

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20. Clarification on the following from SHO #20-003:
    The ONC 21st Century Cures Act final rule also has potential implications for Medicaid agencies, CHIP agencies, Medicaid managed care plans, and CHIP managed care entities. All such entities should review the final rule, particularly the sections on the definition of health information network (HIN) or health information exchange (HIE) and the information blocking exceptions. Those entities should also review existing contractual and financial relationships—especially those related to API usage and access—to evaluate potential compliance implications with regard to the ONC 21st Century Cures Act final rule.
    § 171.102 Definitions.
    Health information network or health information exchange means an individual or entity that determines, controls, or has the discretion to administer any requirement, policy, or agreement that permits, enables, or requires the use of any technology or services for access, exchange, or use of electronic health information:
    (1) Among more than two unaffiliated individuals or entities (other than the individual or entity to which this definition might apply) that are enabled to exchange with each other; and (2) That is for a treatment, payment, or health care operations purpose, as such terms are defined in 45 CFR 164.501 regardless of whether such individuals or entities are subject to the requirements of 45 CFR parts 160 and 164.
    Please clarify how State Medicaid agencies fit the definition of HIN or HIE from the ONC rule and what the implications could be?

MCO Contracts

21. Will CMS be issuing or recommending standard contract language for MCO amendments?

22. What are the expectations for assessing compliance for Medicaid managed care programs?

23. The preamble to the Final Rule states (p 179): *"Medicaid beneficiaries should not be receiving the information from both the state and managed care plan for the same service....The beneficiary should not receive data that is in conflict with other data that is made available through the API."* For states like Colorado that have both FFS and managed care benefits, Colorado would like to provide a state API that provides a holistic patient view of claims and managed care encounters

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data elements. Would that API service satisfy compliance for the managed care plans if they contribute encounters to the state for use in the state API?

Procurement

24. Is CMS open to working with the S-TAG Interoperability Workgroup to leverage NASPO for multi-state procurement?

Payer to Payer Data Exchange

25. Other than ensuring MCO contracts include language requiring MCOs to comply with the Payer-to-Payer data exchange requirements, are State Medicaid/CHIP agencies required to do anything more? Some States have heard that they are required to share beneficiary claims data when a person moves to another State and is found eligible for that new States' Medicaid program.

PROVIDER DIRECTORY API

1. Does the Provider Directory API need to include all providers including individual PCAs?

2. The regulatory text cites provider "specialty" as a required data element. SHO #20-003 "strongly encourage[s] leveraging the DaVinci PDex Plan Net IG" for this API (p. 4). PDex Plan Net defines "PractitionerRole" to include a value set for "Individual and Group Specialties" based on National Uniform Claim Committee (NUCC) provider taxonomies. Could CMS please clarify whether "specialty" in the Provider Directory is expected to include provider type and taxonomy?