Regulatory Updates You Might Have Missed But Should Be Aware Of

Prepared by JFT PRG, LLC for its use and its clients

Key Topics

- Federal Regulatory Interest in AI – ONC and the FDA
- Information Blocking Updates – Provider Disincentives
- Electronic Prior Authorization and HIPAA EDI
- A Word on ICD-11

Federal Interest in Regulating AI

Federal Regulatory Interest in AI

- You have heard a lot about the potential for uses of AI in healthcare and specifically within the revenue cycle – but did you know what the Food and Drug Administration (FDA) and the HHS Office of the National Coordinator for Health IT (ONC) are looking to do to regulate it?
- At a high level
  - The FDA is interested in regulating AI used within Software As a Medical Device (SAMD) and ONC is interested in regulating AI under its HIT Certification Program
    - FDA purpose is in assuring patient safety and efficacy in AI in its role in SAMD
    - ONC purpose is to enforce transparency in AI development, use, and governance
  - FDA Information that follows adapted from Artificial Intelligence/ Machine Learning (AI/ML)-Enabled Medical Devices:

What is Software As a Medical Device? (SAMD)

- Essentially something that is wholly or partly comprised of software that classifies as a medical device
- In the FDA's sense of what makes for a medical device as SAMD, much focuses on the role the software plays in the device function and in the care decision making or delivery process – is it to
  - Inform
  - Drive (e.g.,, recommend)
  - Treat or Diagnose
- Latter two roles are considered to be essential to something being seen as a medical device subject to FDA regulatory oversight

FDA Regulatory Oversight of AI

- FDA is adapting its approach to regulate SAMD to consider role of AI
  - Traditional regulatory approach includes pre-market clearance processes that must be met for FDA to permit marketing of a new medical device and post market surveillance processes to assure medical device is safe and meets intended use
  - Approach for AI includes modifying the traditional approach to account to unique aspects of AI development for both phases of regulatory oversight
    - Major challenge is that traditional approach was defined for evidence-based protocols mostly implemented as static reference data-based models that were "locked" – given input A processed by logic routine B one gets output C
      - They do not "learn" from continuous use –and were not "trained" on data sets but designed based on the evidence base at hand
    - AI based SAMD on the other hand demands continuous monitoring and understanding of how the AI is trained, monitored, and controlled over time

FDA Regulatory Oversight of AI

- In its 2019 white paper on its possible regulatory approach, FDA emphasized four key aspects
  - SAMD manufacturers must follow strong quality systems and good machine learning practices
    - Established quality system similar to what must be in place for medical devices broadly
  - FDA will apply a premarket clearance process for those AI enabled SAMD products that require it
  - FDA will require routine monitoring of SAMD products by manufacturers to determine when a change requires FDA review
    - Would include provision for Predetermined Change Control Plans to govern introduction of future modifications that can support reduction in burden for separate clearance processes for future modifications
  - Regulatory Oversight would include transparency and real world performance monitoring

FDA Regulatory Oversight of AI

- Key Principles to be Upheld AI Models (Paraphrase of Principles Adapted from FDA material)
  - Draw on multi-disciplinary expertise throughout life cycle
  - Follow good software engineering practices including for data quality, risk management, and data management
  - Are designed with equity and fairness in mind with representative populations in training data for intended use so that they are generalizable and controlled for bias
  - Training and test data sets are selected and maintained independent of one another
  - Reference data sets are clinically relevant, and limitations understood
  - Model design reflects intended use and clinical benefits and risks are well understood
  - Human factors are considered for human involvement (How AI supports human performance)
  - Testing generates clinically relevant performance independent of training
  - Transparent information on the AI function is provided to users including for modifications and updates from real world performance monitoring
  - There is ongoing performance monitoring including controls for managing unintended bias, degradation (“drift”) from intended purpose and safety impact

ONC Regulatory Oversight of AI

- As part of HTI-1 Final Rule, ONC Published Revised Criterion at 170.315(b)(11) – Decision Support Interventions (DSI)
  - Compliance date of 1/1/2025 – expiration of current 170.315(a)(9) by 12/31/2024
  - Borrows significantly from what FDA has developed as guidance for SAMD in substance as to process for AI development, training, monitoring, and governance
  - Adopts new requirements to address use of algorithmic/AI based predictive decision support interventions enabled or interfaced to
    - Incorporate health equity by design
    - Enable transparency for how predictive DSI is tested for fairness
    - Enable transparency for how developers of CHIT manage risks related to fairness of predictive DSI
  - Would apply to any Predictive DSI supplied by HIT developer for use with certified module (whether developed by the HIT developer or a third party)
    - Would not include Predictive DSI obtained, or self developed by a customer for use with the certified module
  - Kicker for Revenue Cycle is that the requirement would include all Predictive DSI supplied with certified module but no matter the use case – clinical or administrative
    - If your HIT developer has an integrated suite for clinical and revenue cycle – would reach into the revenue cycle

ONC Regulatory Oversight of AI

- 170.315(b)(11) - DSI
  - Definition of Predictive DSI
    - “Technology intended to support decision-making based on algorithms or models that derive relationships from training or example data and then are used to produce an output or outputs related to, but not limited to, prediction, classification, recommendation, evaluation or analysis”

ONC Regulatory Oversight of AI

- 170.315(b)(11) - DSI
  - Examples of what is Predictive DSI
  - Models that predict if a medical image contains a malignancy based on relationships observed in large data sets.
  - Models that pre-selected a default order from an order set based on relationships in training data.
  - Models that predict risk of sepsis, readmission, suicide risk or other eventualities that are trained based on relationships observed in large data sets often using logistic regression and machine learning techniques to support decision making.
  - Models that generate clinical notes trained on relationships in large data sets of free text including learning language models which support decision making about what to document.
  - Models that use natural language processing to route secure messages are trained based on relationship between message content and individuals responding to similar messages in the past.

ONC Regulatory Oversight of AI

- 170.315(b)(11) - DSI
  - Examples of what is not Predictive DSI
    - Indices and classification systems developed by expert consensus rather than in empirical data – which may be evidence based DSI because they are based on pre-defined rules and not relationships learned from training data.
    - Rules based algorithms for routing secure messages based on the type of message and not relationships in training data.
    - Growth charts are based on an underlying model based on distribution of a single variable rather than a prediction based on relationships between variables.
    - A calculation for Body Mass Index based on an equation rather than relationships in training data.
    - Patient matching algorithms are based on indices of similarities rather than relationships in training data.
    - Optical character recognition is simply used to make a PDF readable and searchable that does not support decision making.

ONC Regulatory Oversight of AI

- 170.315(b)(11) - DSI
  - Transparency as to Data Elements as Inputs as Source Attributes for all DSI possibly through "Model Cards" – "Nutrition Labels for AI" as on what goes in
    - Scoped based on U.S. Core Data for Interoperability (USCDI) Version 3
    - USCDI v3 includes data types important to health equity
      - Patient Demographics data (race, ethnicity, language, sexual orientation and gender identity)
      - SDOH data elements (SDOH Assessment, SDOH Goals, SDOH Problems/Health Concerns and SDOH Interventions)
      - Health Status Assessments data (Health Concerns, Functional Status, Disability Status, Mental or Cognitive Status, Pregnancy Status and Smoking Status)
    - DSI must enable use of all the above as inputs such as for users to define own DSIs or tailor developer supplied DSIs that use any of the indicated data as source attributes using capabilities of the certified module
    - All DSI must be able to be selected/activated by a limited set of users, and source attributes must be able to be accessed or modified by same (and recorded for attributes not specified for Predictive DSI)

ONC Regulatory Oversight of AI

- 170.315(b)(11)- DSI
  - Source Attributes – Reference Information
    - All current requirements from 170.315(a)(9) for evidence based and linked referential CDS – funding source, author, evidence base, etc
    - Additional for predictive DSIs
      - Intervention details – output and intended use of the intervention
      - Development details – input features, training and test data, processes to ensure fairness and external validation processes if available
      - Quantitative measures of performance such as validity and fairness of test data and references on any outcome evaluations
      - Ongoing maintenance of intervention – update schedule, evaluation of intervention as deployed as to validity and fairness

ONC Regulatory Oversight of AI

- 170.315(b)(11)- Predictive DSI - Intervention Risk Management Requirements – Detail and Summary Information
  - Risk Analysis
  - Risk Mitigation
  - Governance

Information Blocking Updates

Reminders About Information Blocking for Providers

- Refresher - What is Information Blocking?
  - Information Blocking is a practice likely to interfere with the access, exchange, or use of electronic health information (EHI) except as required by law or specified in an information blocking exception
  - EHI essentially is the electronic designated record set you should have defined by policy under HIPAA
  - If you have not inventoried what it is and how it is made available from your HIT portfolio – I am happy to have a discussion!
  - Information Blocking Exceptions are "safe harbors" for business practices related to provision of EHI, exceptions permitting withhold of EHI in certain circumstances and dealing with infeasibilities in providing EHI in the manner requested

Reminders About Information Blocking for Providers

- Regulated Actors
  - Health Information Technology Developers
  - Health Information Exchanges
  - Providers
- Different Knowledge Standards
  - HIT Developers and HIEs go by the standard of whether they know or should know the practice at hand is likely to be information blocking
  - Providers go by the standard of knowing if the practice is unreasonable and is likely to be information blocking

Provider Disincentive Proposed Rule

- Lays out information blocking sanctions for providers
  - Would be modeled after the same kinds of consequences as for not being a successful meaningful user
  - For hospitals participating in Promoting Interoperability and Medicare Part A – would result in loss of 75% of annual market basket increase
    - For Critical Access Hospital participants – would result in reduction of reasonable costs to 100% instead of 101%
  - For Eligible Clinicians under the Merit based Incentive Payment Program (MIPS) - would result in a zero score for Promoting Interoperability category of the MIPS Composite Score
  - For Medicare Shared Savings Program ACO provider members – such a provider would be deemed ineligible to participate in the ACO for one year
- In contrast, HIT developers and HIEs face penalties for each separate instance of information blocking violation in amounts up to $1m for the most egregious instances

Provider Disincentive Rule

- Other Key Items
  - A provider cannot be double penalized for failing to be a meaningful user and an information blocker in the same program/calendar year
  - A provider can only be penalized once in a calendar year as an information blocker even if there are multiple violations
  - Effect of the sanction would have the same timing as would failing to be a meaningful user – for example, being found to have been an information blocker in 2025 would result in payment reduction in 2027
  - Only hospitals participating in Part A and Promoting Interoperability, Eligible Clinicians in the Quality Payment Program MIPS and Medicare Shared Savings Program ACOs are impacted under this proposed rulemaking
    - Other types of individual and institutional providers are not within scope of information blocking disincentives at this time

ONC Information Blocking Updates of Interest to Providers From HTI-1 Rule

Prepared by JFT PRG, LLC for its use and its clients

Information Blocking - Definitions

- Offer HIT – Key part of prerequisite requirements to be an HIT Developer subject to information blocking regulation
  - Not defined in initial rulemaking from Cures Act final rule – concerns over lack of clarity of whether being an HIT developer offering HIT applied when
    - Individual or entity that acquired CHIT made it available to be used by others under some manner of donation arrangement(
    - Making available CHIT for use by others in accessing an entity's own production environment
  - It matters to providers who may be HIT developers in own right - Information blocking calls for a more exacting knowledge standard for HIT developers than providers, and more consequential penalties for violations

Information Blocking - Definitions

- Offer HIT - Exclusions from definition
  - Certain donation arrangements that do not limit interoperability or certified capabilities (think Stark and Anti-Kickback HIT safe harbors)
  - Extending CHIT for use by others (clinicians, affiliated individuals or entities) in accessing an entity's production environment
- ONC also is making it explicitly clear self developed CHIT is excluded from Offer HIT as long as for own use

Information Blocking - Definitions

- Offer HIT - Not Excluded from Definition – Any Arrangement In Which
- An individual or entity holds out the HIT for sale, resale, license or relicenses for deployment by or for other individual(s) or entity(ies)
- An individual or entity sells, resells, licenses, relicenses the HIT for deployment by or for other individual(s) or entity(ies)
- An individual or entity otherwise provides or supplies the HIT for deployment by or for other individual(s) or entity(ies)

2024 Advancing Interoperability and Improving Prior Authorization Processes Final Rule (CMS-0057-F)

Prior Authorization

- CMS's requirements will apply to any formal decision-making process for impacted payers to make authorization decisions for enrollees
  - Exception – would not apply to decisions regarding medications dispensed, administered or prescribed to enrollees
- Compliance date for API requirements would be January 1, 2027
- Will require an HL7 Fast Healthcare Interoperability Resources (FHIR) Application Programming Interface (API) to implement what is called the "Prior Authorization API"

Prior Authorization

- Prior Authorization API Functions
  - Allow a provider to query the payer's system to determine whether a prior authorization was required for certain items and services
  - Allow a provider to identify documentation requirements related to the requested item or service
  - Allow for compilation of the necessary data to populate the HIPAA compliant prior authorization transaction request including for provision of supporting documentation
  - Enable payers to provide status of the prior authorization request including whether the request had been approved (and for how long) or denied with the reason for denial
  - Support transformation of a API based prior authorization request into a HIPAA compliant 278 request and back for provider to payer and payer to provider transacting

Prior Authorization

- Prior Authorization API Recommended IGs – CMS is recommending but not requiring use of the following Da Vinci IGs to support the Electronic Prior Authorization API
  - HL7 FHIR Da Vinci Coverage Requirements Discovery (CRD) Implementation Guide (IG)
    - Would support coverage requirements discovery for items and services provider to payer
  - HL7 FHIR Da Vinci Documentation Templates and Rules (DTR) IG
    - Would provide information on what documentation would be necessary for supporting the request for the item or service
  - HL7 FHIR Da Vinci Prior Authorization Support (PAS) IG
    - Would support compilation, assembling, and formatting of necessary supporting documentation for the request
    - Would support transformation of request into HIPAA standard transaction and back and support communication of payer decision through an intermediary
    - Would support ongoing interactions for a request including follow up on the status of, revision to, or cancellation of a previous request

Considerations for Certification

- CMS adopted a requirement for the MACRA QPP MIPS Promoting Interoperability Category and for the Hospital Promoting Interoperability program for Medicare to include a measure related to requesting a prior authorization electronically for at least 1 item or service during the PI reporting period (90 days)
  - The request would be done using the Prior Authorization API
  - The data used for the request would have to come from Certified EHR Technology (CEHRT)
  - The measure would be an attestation (Y/N) measure
  - The measure would be implementing for CY 2027/Payment Year 2029

Considerations for Certification

- Thoughts related to certification
  - Electronic prior authorization is expected to be included in ONC's pending HTI-2 proposed rule due later in 2024
  - Seems clarity still needed for "using data from CEHRT". Not all data necessary for a prior authorization likely to come from CEHRT as some is revenue cycle data not clinical EHR data – CMS did not really address this
  - Prior authorization involves many different types of HIT for a provider – clinical, revenue cycle (scheduling, registration, practice management, patient accounting, eligibility verification….)
    - Also many types of payer HIT
    - If there were to be certification requirements for electronic prior authorization processing – would it involve provider and payer HIT since the Prior Authorization API may be stood up by a payer?

2022 Administrative Simplification – Healthcare Attachments, Electronic Signatures and Modifications to Referral Certification and Authorization Transaction Proposed Rule (CMS-0053-P)

Background

- Claims Attachment standard the one standard transaction required by the original HIPAA statute never adopted under rulemaking
- CMS had first attempted rule making for a claims attachment standard based on HL7 CDA r1 in 2005 that would have implemented a number of attachment templates for specific healthcare use cases
- HHS also proposed an electronic signature rule in 1998 that was also never finalized
- Both the prior two items are being proposed under this rulemaking

Definition Changes

- CMS is proposing to move away from the limiting construct of claims attachment to "attachment information" and "healthcare attachment" to reflect the intent that attachments can be for multiple HIPAA EDI standard transactions
  - In this rulemaking, CMS is focused on its use to support healthcare claims and prior authorization requests conducted using the X12 ANSI standards
  - This would apply to documentation not included in a claim or prior authorization transaction that is necessary for a health plan to make a decision such as to adjudicate a claim or approve a prior authorization request
  - This would apply to "solicited" (payer requested) and "unsolicited" (provider supplied absent a payer request) use cases for attachment information
  - CMS acknowledges that there are other use cases such as for provision of audit documentation, to support utilization review or medical necessity or other purposes that payers may seek clinical information to support but such are out of scope of this rulemaking

Electronic Healthcare Attachments

- CMS is proposing two X12 Technical Report Type 3 implementation specifications for health plans to request attachment information
  - X12N 277 – Health Care Claim Request for Additional Information (006020X313) to be used by a health plan to electronically request attachment information for a claim
    - The X12N 277 contains the health plan assigned claim control number to enable document reassociation to the healthcare claim when the provider sends the healthcare attachment to the health plan
    - The X12N 277 also contains a LOINC code to idemtify the specific attachment information the health plan is seeking
  - X12N 278 – Health Care Services Request for Review and Response (006020X315) to be used by a health plan to electronically request attachment information for a prior authorization request

Electronic Healthcare Attachments

- CMS is proposing one X12 Technical Report Type 3 transaction for the transmission of attachment information with two sub transactions
  - X12N 275 – Additional Information to Support a Health Care Claim or Encounter
  - X12N 275 – Additional Information to Support a Health Care Services Review (for use for prior authorizations)
  - The X12N 275 transactions can be used for both solicited and unsolicited attachment information

Electronic Healthcare Attachments

- CMS is proposing three HL7 implementation specifications for the actual content of the attachment
  - HL7 Implementation Guide (IG) for CDA Release 2 (R2): Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use (DSTU) Release 2.1, Volume 1 – Introductory Material, June 2019 with Errata (C-CDA 2.1)
  - HL7 IG for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) DSTU Release 2.1, Volume 2 – Templates and Supporting Materiel, June 2019 with Errata (C-CDA 2.1)
    - Volume 1 and 2 collectively describe how to construct structured document templates defined by HL7
    - Volume 1 and 2 also provide guidance to construct an unstructured document template when HL7 has not defined one
  - HL7 CDA R2 Attachment IG: Exchange of C-CDA Based Documents, Release 1, March 2017
    - This provides guidance on how to construct electronic health care attachments and to attach and send the attachment information using the X12N health care attachment standards
    - The IG also includes instructions for the use of LOINC codes to request attachments health plan to provider or to identify the attachments documentation templates for transmission provider to health plan

Electronic Signatures

- CMS is proposing a digital signature requirement for health care attachments as the electronic signature method to be used
- CMS is proposing a definition for electronic signature that it is a "electronic sound, symbol, or process, attached to or logically associated with attachment information and executed by a person with the intent to sign the attachment information"
- CMS is also proposing that the electronic signature must support user authentication, message integrity and non-repudiation
- CMS is proposing the HL7 Implementation Guide for CDA Release 2: Digital Signatures ad Delegation of Rights, Release 1 as the specification for digital signature

Electronic Signatures

- CMS is not proposing
  - A particular signature path or workflow for how health care attachments are electronically signed or by who
  - Any other application of an electronic signature requirement to any other health care process within a provider

Update to Referral Certification and Authorization Transaction X12N 278

- CMS is proposing to update the HIPAA EDI standard transaction for Referral Certification and Authorization to the 6020 version from the 5010 version
  - This coincides with the use of 6020 for all other proposals within this rulemaking for the 275 health care attachment related proposals
  - Updating the 278 to the 6020 version allows for two important requirements to be met not supported under 5010
    - Expanding support for a health care provider to specifically indicate a missing tooth, extracted tooth, tooth to be extracted, or impacted tooth in a health care referral certification and authorization transaction for a patient to see a dental provider
    - Revising and expanding support for a drug authorization including fields necessary to identify a drug, specify the quantity of a drug requested, specify drug dosage requested, and to accommodate related procedure codes

Compliance Date

- The compliance date for this rule would be 24 months after the effective date of a final rule

An Interesting Note

- There is an odd overlap with the proposed Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule
  - Where that proposed rule and this proposed rule overlap, impacted health plans under both would be subject to both
  - One takes an API based approach for health care attachments for electronic prior authorization requests with the PARDD API, and one takes an HL7 CDA based approach
    - Granted that the Prior Authorization API approach would also allow for going from HL7 FHIR to a 278 transaction and back presumably with the attendant health care attachment as well, but it seems oddly unwieldy to require that it occur under the other rule
    - It may preview a movement some day to a FHIR API based approach to HIPAA EDI

So Voila….Now We Also Have This

- HHS and CMS may have been reading along with me – on February 28, 2024, HHS announced enforcement discretion to allow use of HL7 FHIR standard (see CMS-0057-F!) for HIPAA EDI Referral Certification and Prior Authorization for HIPAA Covered Entities
  - Would seem to allow for the overlap but resolve the possible duplication posed by CMS-0057-F and CMS-0053-P)
  - It would apply to any HIPAA covered entity (provider, health plan, or clearinghouse) and not just those subject to the requirements of CMS-0057-F
  - It would apply as soon as any covered entity engages in electronic prior authorization using the FHIR standard (and not just only as of the compliance date of CMS-0057-F)

https://www.cms.gov/files/document/discretion-x12-278-enforcement-guidance-letter-remediated-2024-02-28.pdf

And Not Likely the End of a Couple of Trends Emerging

- In CMS-0053-P, we now see individual HIPAA standard transactions advance versus a full upgrade of the full transaction set for X12 versions
- We also see advocacy for the use of FHIR as an alternate basis for a HIPAA EDI standard – in its March 2022 transmittal letter to the Secretary, the NCVHS advocated that
  - "Recommendation 3: HIPAA transaction rules notwithstanding, evaluate and adopt regulatory flexibility strategies to permit HIPAA Covered Entities to implement new technologies such as FHIR standards and implementation guides (IGs)."

A Word on ICD-11

Prepared by JFT PRG, LLC for its use and its clients

ICD-11

- Obviously, nothing imminent!
- Last update from NCVHS
  - Original recommendations letter to Secretary in 2019 and updated by 2021 letter
  - Recommended that HHS conduct research to evaluate approaches to transition and implementation with focus on minimizing burden and costs – high concern with false starts for ICD-10
  - ICD 11 has been in place for several years for mortality reporting as per World Health Organization requirements
  - Compelling question is will a clinical modification be needed for adoption for US health care payments use
  - Would ICD 11 be the last major scale ICD update? Supposedly would allow for continuous updates
- My prediction? No proposed rulemaking before 2025 with no implementation target before 2027

Questions?

MY CONTACT INFORMATION – JFTPRGLLC@YAHOO.COM