Grab Bag: Hot Health Law Topics Presented in a "Beach-Read" Format

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August 10, 2016

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Fraud, Waste and Abuse and Compliance Training

- Lots of lingo, very complicated regulations.
- Plans say hospitals and clinics are “first tier downstream and related entities” (“FDR”).
- Plans may expect you to perform fraud, waste and abuse training and compliance training.
- They cite 42 C.F.R. 422.503 (b)(4)(vi)(C) and 423.504 (b)(4)(vi)(C).

42 C.F.R. 422.503 (b)(4)(vi)(C)

(b) Conditions necessary to contract as an MA organization. Any entity seeking to contract as an MA organization must:

(4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following:

(vi) Adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements:

42 C.F.R. 422.503 (b)(4)(vi)(C)

(C) (1) Each MA organization must establish and implement effective training and education between the compliance officer and organization employees, the MA organization's chief executive or other senior administrator, managers and governing body members, and the MA organization's first tier, downstream, and related entities. Such training and education must occur at a minimum annually and must be made a part of the orientation for a new employee, new first tier, downstream and related entities, and new appointment to a chief executive, manager, or governing body member.

(2) First tier, downstream, and related entities who have met the fraud, waste, and abuse certification requirements through enrollment into the Medicare program are deemed to have met the training and educational requirements for fraud, waste, and abuse.

42 C.F.R. 422.503 (b)(4)(vi)(C)

(3) An MA organization must require all of its first tier, downstream, and related **entities** to take the CMS training and accept the certificate of completion of the CMS training as satisfaction of this requirement. MA organizations are prohibited from developing and implementing their own training or providing supplemental training materials to fulfill this requirement.

Things to Note

- Regulations refer to “the CMS training” without defining it.
- Regulations say Medicare suppliers and providers are exempt from FWA training.
- The reference to “CMS training” comes after this waiver.
- How does an “entity” train?

General Compliance Training

- Sponsors must ensure that general compliance information is communicated to their FDRs. The sponsor's compliance expectations can be communicated through distribution of the sponsor's Standards of Conduct and/or compliance policies and procedures to FDRs' employees. Distribution may be accomplished through Provider Guides, Business Associate Agreements or Participation Manuals, etc.
  - Medicare Managed Care Manual Ch. 21 Sec. 50.3.1

The Complication

- The Manuals haven’t been updated since the regulations.
- The regulations and Manuals don’t really apply directly to you.
- “Your contract controls!”

Who “must” train?

In order to prevent unnecessary burden on FDRs, Sponsors should work with their FDRs and specify which positions within an FDR must complete the training. There will be certain FDRs where not every employee needs to take the training based on their duties.

Below are examples of the critical roles within an FDR that should clearly be required to fulfill the training requirements:

Positions/Roles

Senior administrators or managers directly responsible for the FDR’s contract with the Sponsor (e.g. Senior Vice President, Departmental Managers, Chief Medical or Pharmacy Officer);

Individuals directly involved with establishing and administering the Sponsor’s formulary and/or medical benefits coverage policies and procedures;

Who "must" train?

Individuals involved with decision-making authority on behalf of the Sponsor (e.g. clinical decisions, coverage determinations, appeals and grievances, enrollment/disenrollment functions, processing of pharmacy or medical claims);

Reviewers of beneficiary claims and services submitted for payment; or,

Individuals with job functions that place the FDR in a position to commit significant noncompliance with CMS program requirements or health care FWA.

- CMS Memo; Additional Guidance – Compliance Program Training Requirements and Audit Process Update – December 28, 2015

Do Medicare Rules Apply to MA Patients?

- No regulation expressly suggests this.
- Each program points a finger at the other.
- Review your payer agreement and provider manual.
- Stark may be a different story.

Ransomware and HIPAA

- New guidance from OCR on July 11, 2016.
- What is ransomware and why does OCR care about it?
- Average of 4,000 daily attacks since early 2016 (300% increase in attacks in 2015).

Avoid, Mitigate Ransomware Attacks AND Comply with HIPAA

- Security risk analysis: Specifically include ransomware as a line item.
- Contingency plan:
  - Backup frequently (consider offline and unavailable from networks); and
  - Test backup recovery process.
- Treat ransomware as you would a “security incident” and follow your HIPAA security incident response plan and procedures immediately upon detection.
- Train workforce on early signs of ransomware.

Do you have to report a ransomware attack?

- Is the PHI unsecured?
  - OCR says a ransomware attack of an encrypted computer that is not powered down could be a breach of unsecured PHI.
- Is there a low probability the information has been compromised?
  - Now, two additional factors to consider:
    - 1) High risk of unavailability of data?
    - 2) High risk to the integrity of the data?
    - "In those cases, entities must provide notification to individuals without unreasonable delay, particularly given that any delay may impact healthcare service and patient safety."

Ransomware and HIPAA

- Read the guidance here: http://www.hhs.gov/sites/default/files/RansomwareFactSheet.pdf

Does the 60-Day Report and Return Provision Apply?

- It definitely applies to payments received by the plan from the government.
- Less clear whether it applies to payments from plans to providers and suppliers.
- Better safe than sorry?

60 Day Rule: 42 CFR § 401.305(a)(2)

"A person has identified an overpayment when the person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment. A person should have determined that the person received an overpayment and quantified the amount of the overpayment if the person fails to exercise reasonable diligence and the person in fact received an overpayment."

What Is Knowingly?

"While we acknowledge the terms 'knowing' and 'knowingly' are defined but not otherwise used in Section 1128J(d) of the Act, we believe that Congress intended for Section 1128J(d) of the Act to apply broadly. If the requirement to report and return overpayments only applied to situations where the providers or suppliers had actual knowledge of the existence of an overpayment, then these entities could easily avoid returning improperly received payments and the purpose of the section would be defeated."

- 81 FR 7660

Is Six Years Right?

"*Overpayment* means any funds that a person has received or retained under title XVIII of the Act to which the person, after applicable reconciliation, is not entitled under such title."

- 42 CFR 401.303

•If the contractor can't reopen the claim, doesn't that mean you are entitled to keep the money?

Six Years From When?

- Remember “identify” includes quantification.
- The six years runs from the date the overpayment is quantified not from the first suspicion of an overpayment.
- Operationally, this may be challenging.

Phase 2 HIPAA Audits: What's the status?

- Audits are a "compliance improvement activity" aimed at education and identifying areas where guidance is needed.
- On July 11, 2016, OCR notified 167 covered entities, selected at random, of their Phase 2 audit participation.
- Desk audits are underway. Onsite audits begin early 2017 (smaller group).
- Business Associate audits will begin in September.

Phase 2 HIPAA Audits: What's the status?

Read more here: http://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/audit/index.html.

Phase 2 HIPAA Audits: Topics Audited

- Privacy Rule.
  - Notice of Privacy Practices – content and provision of notice.
  - Right of access to records.
- Breach Notification.
  - Timeliness of notification.
  - Content of notice.
- Security Rule.
  - Risk Analysis.
  - Risk Management.

OCR Guidance: Right to Access

- In January and February 2016, OCR released guidance documents (Fact Sheet and two sets of FAQs) regarding an individual's right to access his/her PHI records.
- Covers many topics:
  - Written requests;
  - What is "unreasonable" in terms of getting access (e.g., web portal);
  - Electronic access (e.g., email); and
  - Fees, fee limits, and requests for copies to third parties (e.g., attorneys).

OCR Guidance: Right to Access

Read it here:
http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html

Medicare Appeals Process

- Proposed Rule https://www.federalregister.gov/articles/2016/07/05/2016-15192/medicare-program-changes-to-the-medicare-claims-and-entitlement-medicare-advantage-organization.
- Comment through 8/29.

Medicare Appeals Process

- 750,000 pending ALJ appeals. 77,000 a year resolved, additional capacity of 15,000 planned.
- AHA litigation prompts judge to ask for a plan.
- Many wording changes. MAC/Board v. Council and filed v. submitted.

Medicare Appeals Process

- Make some Council decisions precedential.
- Allow attorney adjudicators.
- Statistical sampling appeal date based on last case in the bunch.

OPPS Proposal for Provider-Based Payments

- Bipartisan Budget Act of 2015 (BBA15) generally limits OPPS payments beginning 1/1/2017 to only those off-campus provider-based departments (PBDs) billing as hospital departments on or before 11/1/2015 that
  - Remain at the same physical address and
  - Furnish the same service lines it offered on or before 11/1/2015.

OPPS Proposal for Provider-Based Payments

- Expecting the final OPPS rule in November.
- In the meantime, there are a number of issues/questions with the OPPS proposed rule implementing BBA15.

OPPS Proposal for PBDs - Issues

- Proposal not to pay hospitals at all for non-excepted PBDs during CY 2017.
  - CMS: “No mechanism to allow an off-campus PBD to bill and be paid as another provider or supplier type using a non-institutional claim form.”
  - Physicians are to bill for all services on the 1500 with a non-facility POS code and presumably divide with the hospital . . . !
- What is “off-campus”?
  - Dependent on what is a “main building” (for 250 yard calculation).
  - No further definition of “campus” or other terms.
  - Vagueness may be our friend. Remember that the CMS Regional Office is given discretion in the text of the provider-based regulation.
  - CMS maintains its position that a hospital may have only one main campus.

OPPS Proposal for PBDs - Issues

- An excepted off-campus PBD that relocates would lose its excepted status.
  - The excepted location is “the physical address that was listed on the provider’s hospital enrollment form as of 11/1/2015” and **includes any “unit number.”**
  - Can you change your footprint (e.g., add a floor or rooms) at the same physical address?
  - Presumably you can move to the main campus . . .
  - Right now, all hinges on the CMS-855A that may have been submitted years ago and/or with incorrect information.

OPPS Proposal for PBDs - Issues

- Proposal seems to except only those service lines for which the PBD actually billed as of 11/1/2015. Attempted to establish 19 “clinical families of services” defined by APC group number.
  - There is no support for this in the statute or regulation.
- Changes in ownership.
  - Retain excepted status after a change in ownership “only if ownership of the main provider is also transferred and the Medicare provider agreement is accepted by the new owner.”

340B Update

- Proposed omnibus rule on the actual 340B program in 2015. Still expect final rule from HRSA in 2016.
- Other new regulations affecting 340B: Medicaid managed care.
  - Medicaid managed care plans required to exclude utilization data for drugs subject to 340B discount so drug manufacturers will not be subject to a "duplicate discount." This will affect claims – will need to identify the 340B drugs.

340B Update

- OPPS proposed rule implementing site neutrality requirements.
- CMS requested comments on enrollment of off-campus clinics on cost reports. Will HRSA follow CMS to make sure off-campus clinics can still get 340B discounts?

IPPS Rule

- Admission that 2-midnight rule may not increase admissions.
- “The commenter stated that use of Condition Code 44 is not rare and despite the 2-midnight policy, patients who remain in the hospital for multiple days often are coded as outpatients.”

MOON

- MOON = Medicare Outpatient Observation Notice.
- On 8/2/16, in the IPPS, CMS finalized the MOON reg.
  - Must be provided no later than 36 hours after the observation services are initiated (or sooner if individual is transferred, discharged, or admitted as an inpatient).
  - Must be signed by the patient or the patient's representative (or document the refusal to sign).
  - Must be accompanied by a verbal explanation.
- Can you provide it prior to 24 hours?
  - Yes, but don't provide to too early (i.e., at the initiation of the observation services).
- Delayed implementation: 90 days after final rule to implement the use of the MOON (final rule expected 10/1/2016).
- MOON form is still being approved by CMS and the OMB.

Proposed Cardiac Bundling

- https://www.federalregister.gov/articles/2016/08/02/2016-17733/medicare-program-advancing-care-coordination-through-episode-payment-models-epms-cardiac.
- Comment through October 3.

Episode Payment Model

- Applies to heart attacks (myocardial infarction or MI), coronary artery bypass graph (CABG) surgery and surgical hip/femur fracture treatment (SHFFT).
- Hospital responsible for care 90 days post discharge.

Episode Payment Model

- 5 year program, starting 7/1?
- Mandatory in select MSA.
- 98 MSAs chosen from 294.
- Within MSA, possible exceptions will be BPCI Model 2 and 4 for hip and femur procedures except major joint.

Episode Payment Model

- Target price based on hospital and regional history and quality components.
- Target 1/3 regional year 1, all regional by year 4.
- Historic rate reduced by 1.5 to 3 percent, lower reduction for higher quality hospitals.

Episode Payment Model

- “Related” care is bundled.
- Physician work, rehab, drugs, and hospital readmissions.
- What about hospice care??

Episode Payment Model

- Keep savings, ("reconciliation payment") responsible to pay for overage ("repayment") up to cap.
- Year 1, 5% cap on gain, no risk. Cap +/- 10% by year 3, 20% Year 4 and 5.
- May enter collaboration agreements.
- Others not required to agree.
- Patients have total freedom of choice.

Episode Payment Model

- Quality criteria are important.
- Failing to hit metrics voids entire reconciliation payment.

MI

- MORT-30-AMI: Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0230).
- AMI Excess Days: Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction (acute care days include emergency department, observation, and inpatient readmission days); and
- HCAPHS Survey (NQF #0166), linear mean roll-up (HLMR) scores like CJR.

CABG

- MORT-30-CABG: Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft Surgery (NQF #2558) and
- HCAPHS Survey (NQF #0166).

SHFFT

- THA/TKA Complications: Hospital-Level Risk-Standardized Complication;
- Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee;
- Arthroplasty (TKA) (National Quality Forum [NQF] #1550);
- Hospital Consumer Assessment of Healthcare Providers and Systems (HCAPHS)
- Survey (NQF #0166); and
- Successful Voluntary Reporting of Patient-Reported Outcomes.

Quality Point System

- CABG score of 2.8 to get payment. This means: 1) achieve the 30th percentile on the RSMR Following Graft (CABG) measure, 2) achieve the 40th percentile on the HCAHPS or 3) have improvement that is better than 90% of other hospitals in the program.
- HCAPHS and bathrooms.

Cardiac Rehab

- Tested in 45 regions in the bundled program, 45 regions outside.
- Extra $25 for first 11 CR visits, $175 each visit thereafter.

False Claims Act Penalties

- Effective August 1, 2016, increased from $5,500-$11,000 per claim to **$10,781-21,563 per claim**.
- Applies to violations after November 2, 2015.
- Annual inflationary adjustments based on CPI will take effect starting January 15, 2017 (although DOJ may enact a smaller increase in its discretion).

Does the FCA Apply to Claims to MA Plans?

- Assume the answer is yes but …
- Fight vigorously to argue the answer is no.

Universal Health Services v. United States ex rel. Escobar

- Care by unlicensed “professionals”?
- Implied Certification case.
- Conditions of Payment v. Conditions of participation?
- Opted for a materiality standard.

Universal Health Services v. United States ex rel. Escobar

- "Likewise, if the Government required contractors to aver their compliance with the entire U. S. Code and Code of Federal Regulations, then under this view, failing to mention noncompliance with any of those requirements would always be material. The False Claims Act does not adopt such an extraordinarily expansive view of liability."

Accessible Websites

- New rule interpreting the ACA require health care entities that receive federal financial assistance to have websites that are accessible to individuals with disabilities, unless there is an undue burden.
- But the rule doesn't specify a website accessibility standard!
- Guidance suggests the WCAG 2.0 AA standards or the Section 508 standards.

QUESTIONS?

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