HLP

THE HEALTH LAW PARTNERS

LEGAL TEAM – WHEN ALL ELSE FAILS

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OVERVIEW

- Push through payor abuse to affect change
- Strategies and hot topics with payor audits
- How do you know when it is time to stop appealing

PUSH THROUGH PAYOR ABUSE TO AFFECT CHANGE

- Role of legal counsel
  - Compliance education
  - Negotiating with payors
  - Contract rights and legal action options
  - Input regarding appeals

HOT TOPICS WITH PAYOR AUDITS

- High stakes
  - U.S. v. Prime Healthcare Services, Inc.
    - 2014 WL 12480026
    - https://www.justice.gov/opa/pr/united-states-intervenes-false-claims-act-lawsuit-against-prime-healthcare-services-inc-and
  - U.S. v. Health Management Associates
    - E.g., 22 F. Supp. 3d 1210
    - https://www.justice.gov/opa/pr/government-intervenes-lawsuits-against-health-management-associates-inc-hospital-chain
  - U.S. v. Community Health Systems, Inc.
    - 501 F.3d 493
    - https://www.justice.gov/opa/pr/community-health-systems-inc-pay-9815-million-resolve-false-claims-act-allegations

HOT TOPICS WITH PAYOR AUDITS

- ALJ backlog persists
- As of April 2017, the backlog of appeals pending at the Administrative Law Judge (ALJ) level consisted of approximately 650,000 claims by more than 700 providers, totaling approximately $6.6 billion.
- The most recent data available (2nd Qtr 2017) shows that the average processing time for a Request for ALJ hearing has increased to 1,057.2 days.
  - https://www.hhs.gov/about/agencies/omha/about/current-workload/average-processing-time-by-fiscal-year/index.html

HOT TOPICS WITH PAYOR AUDITS

- New Medicare Appeals regulations
  - On January 17, 2017, the Department of Health and Human Services (HHS) issued a Final Rule entitled, "Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures."
    - 82 Fed. Reg. 4974 (January 17, 2017), *available at* https://www.federalregister.gov/documents/2017/01/17/2016-32058/medicare-program-changes-to-the-medicare-claims-and-entitlement-medicare-advantage-organization
    - 42 C.F.R. §405, Subpart I: https://www.ecfr.gov/cgi-bin/text-idx?SID=bb361042e3b1a501ca84abde8d3a61a9&mc=true&node=pt42.2.405&rgn=div5#sp42.2.405.i
  - The Final Rule was effective March 20, 2017

CONTENTS OF THE FINAL RULE

- General Provisions
  - Precedential final decisions of the Secretary
  - Attorney Adjudicators
- Specific Provisions
  - Appointed Representatives
  - CMS and/or CMS contractors as participants or parties to the adjudication process
  - Requests for ALJ hearing
    - Content of requests for ALJ hearing
    - Sending copies
    - Place for a hearing
    - Notice of hearing/issues
    - Hearing procedures

PRECEDENTIAL FINAL DECISIONS OF THE SECRETARY

- Previously, Medicare Appeals Council (Council) decisions were binding only on the parties to a particular appeal; they did not have precedential value.
- The Final Rule grants precedential authority to *certain* Council decisions.
- The Chair of the Department Appeals Board (DAB) is tasked to designate which Council decisions will be made precedential.
- Notice of decisions designated as precedential will be made through the Federal Register and posted on a page on HHS' website.
- Precedential Council decisions are binding on all lower-level decision makers from the date that they are posted on HHS' website.

PRECEDENTIAL FINAL DECISIONS OF THE SECRETARY 42 C.F.R. §401.109

- In applying precedential Council decisions:
  - (1) The Council's legal analysis and interpretation of an authority, binding provision, or provision that is owed substantial deference is binding on future determinations where the same authority or provision is applied (and remains in effect);
  - (2) Factual findings are binding and must be applied to future determinations and appeals involving the same parties if the relevant facts remain the same.
    - E.g., if a precedential Council decision made findings of fact related to the issue of whether an item qualified as DME and the same issue was in dispute in another appeal filed by the same party (and that party submitted the same evidence to support its assertion), the findings of fact in the precedential Council decision would be binding.

PRECEDENTIAL FINAL DECISIONS OF THE SECRETARY 42 C.F.R. §401.109

- The goal of granting precedential authority to certain Council decisions is to provide adjudicators with direction on repetitive issues and increase predictability for appellants throughout the appeals process to guide their decision-making regarding which claims to appeal.

- **42 C.F.R. §401.109(a).** In determining which decisions should be designated as precedential, the DAB chair may take into consideration decisions that address, resolve or clarify recurring legal issues, rules or policies, or that may have broad application or impact, or involve issues of public interest.

PRECEDENTIAL FINAL DECISIONS OF THE SECRETARY 42 C.F.R. §401.109

- To ensure consistent application of precedential Council decisions, HHS intends to perform joint training sessions involving the Council, OMHA and CMS to educate adjudicators at each level of appeal regarding the decisions.

- As for the appellant community, HHS stated that "education sessions may also be appropriate during forums where the public participates, such as the OMHA Appellant Forum."

ATTORNEY ADJUDICATORS

- The Final Rule grants authority for Attorney Adjudicators (AAs) to issue decisions where an ALJ hearing is not required. ALJs will retain sole responsibility for presiding over ALJ hearings.

- Examples of situations in which AAs may issue decisions (i.e., where an ALJ hearing is not required):
  - (1) (a) Where the evidence in the hearing record supports a finding in favor of the appellant(s) on every issue; (b) if the parties agree in writing they do not wish to appear before an ALJ at a hearing; and/or (c) if a stipulated decision is appropriate
  - (2) Where an appellant requests to withdraw its Request for ALJ hearing
  - (3) Where an appellant appeals a QIC dismissal
  - (4) Where remand to a Medicare contractor is appropriate to obtain information that can only be provided by CMS or its contractors

- HHS estimates that based in FY 2016 data, the addition of AAs could redirect 24,500 appeals per year from the dockets of ALJs, to be decided at a lesser cost to the government.

STIPULATED DECISIONS

- In its Final Rule, HHS acknowledged situations where a CMS contractor participates in the proceedings before an ALJ and acknowledges either orally or in writing that an appealed item or service should be covered. The Final Rule states that such situations are "ideal" for stipulated decisions and provides authority for an ALJ or AA to issue stipulated decisions in such cases "in lieu of full decision[s] that [include] findings of facts, conclusions of law and other decision requirements."
- However, even if a CMS contractor indicates that it believes an appealed item or service should be covered, an ALJ or AA is not required to issue a stipulated decision; rendering a stipulated decision is optional.

APPOINTED REPRESENTATIVES
42 C.F.R. §405.910

- Prior to enactment of the Final Rule, *sub-regulatory guidance* (i.e., the Medicare Claims Processing Manual (CMS Internet-Only Publication 100-04), Chapter 29, Section 270.1.2 and CMS Form 1696 (Appointment of Representative (AOR) form)) required a valid AOR to include a unique identifier of the individual or entity represented (i.e., a HICN if a beneficiary is the represented party *and the NPI if a provider or supplier is the represented party*). The *regulations* did not require that a valid AOR contain the NPI of a represented provider or supplier.
- The Final Rule revised the regulations to mirror sub-regulatory guidance to require that where a represented party is a provider or supplier, a valid AOR must include the NPI of that provider or supplier.

CMS AS PARTICIPANT / PARTY
42 C.F.R. §§405.1010 AND 405.1012

- Prior to enactment of the Final Rule, there were no limitations in place on the number of CMS contractors that were permitted to participate in ALJ hearings (which created challenges to schedule ALJ hearings and resulted in lengthier proceedings with oftentimes duplicative testimony).
- In its Final Rule, HHS placed limits on the number of CMS contractors that are permitted to serve as a participant or party in an ALJ proceeding and clarifies the roles for hearing participants and parties.

CMS AS PARTICIPANT / PARTY
42 C.F.R. §§405.1010 AND 405.1012

	Non-party Participant **42 C.F.R. §405.1010**	**Party** **42 C.F.R. §405.1012**
When may a CMS contractor elect this status?	There are three opportunities: (1) If no hearing is scheduled, no later than 30 calendar days after notification that a request for hearing was filed; (2) If a hearing is scheduled, no later than 10 calendar days after receiving the notice of hearing; (3) An ALJ may request, but not require, CMS and/or one or more of its contractors to participate in an ALJ hearing.	There are two possibilities (unless the request for hearing is filed by an unrepresented beneficiary, in which case CMS and its contractors would be precluded from electing party status): (1) Upon filing a notice of intent to be a party no later than 10 calendar days after the QIC receives the notice of hearing (2) An ALJ may request, but not require, CMS and/or one or more of its contractors to be a party to a hearing.

CMS AS PARTICIPANT / PARTY
42 C.F.R. §§405.1010 AND 405.1012

	Non-party Participant **42 C.F.R. §405.1010**	**Party** **42 C.F.R. §405.1012**
What are a CMS contractor's roles and responsibilities in the proceedings on a request for ALJ hearing?	Participation **includes** filing position papers and/or providing testimony to clarify factual or policy issues in a case. Participation **does not include** calling witnesses or cross examining the witnesses of a party to the hearing. However, the parties may provide testimony to rebut factual or policy statements made by a participant.	Parties may file position papers, submit evidence, provide testimony to clarify factual or policy issues, call witnesses and/or cross examine the witnesses of other parties.

CMS AS PARTICIPANT / PARTY
42 C.F.R. §§405.1010 AND 405.1012

	Non-party Participant **42 C.F.R. §405.1010**	**Party** **42 C.F.R. §405.1012**
Limitation on participating in a hearing	**If a CMS contractor has been made a party to a hearing**, no entity that elected to be a participant in the proceedings may participate in the oral hearing, but such entity may file a position paper and/or written testimony to clarify factual or policy issues. **If a CMS contractor did not elect to be a party to a hearing and more than one entity elected to be a participant in the proceedings**, only the first entity to file a response to the notice of hearing may participate in the oral hearing. Entities that filed a subsequent response to the notice of hearing may not participate in the oral hearing, but may file a position paper and/or written testimony to clarify factual or policy issues in the case. If a CMS contractor is precluded from participating in the oral hearing, the ALJ may grant leave to the precluded entity to participate in the oral hearing if the ALJ determines that the entity's participation is necessary for a full examination of the matters at issue. If the ALJ does not grant leave to the precluded entity to participate in the oral hearing, the precluded entity may still be called as a witness by CMS or a contractor that is a party to the hearing.	If a CMS contractor or multiple contractors file an election to be a party to the hearing, the first entity to file its election after the notice of hearing is issued is made a party to the hearing, and the other entities are made participants in the proceedings, unless the ALJ grants leave to an entity to also be a party to the hearing. An ALJ may grant leave to an entity to be a party to the hearing if the ALJ determines that the entity's participation as a party is necessary for a full examination of the matters at issue.

CONTENTS OF REQUEST FOR ALJ HEARING
42 C.F.R. §§405.1014

- In correlation with the Final Rule, in January 2017, Form CMS-20034 A/B "Request for Medicare Hearing by an Administrative Law Judge" was discontinued and replaced with Form OMHA-100, "Request for an Administrative Law Judge (ALJ) Hearing or Review of Dismissal."

EVIDENCE SUBMITTED WITH REQUEST FOR ALJ HEARING 42 C.F.R. §§405.966

- Federal regulations include an early presentation of evidence requirement, which (absent good cause) prohibits new evidence from being submitted at the ALJ stage of appeal if it was not submitted at or prior to reconsideration.

- The Final Rule identifies 4 circumstances in which good cause for submitting new evidence at the ALJ level may be found (and limits good cause to these 4 situations):
  - (1) When the ALJ or AA determines that new evidence is material to an issue addressed in the QIC's reconsideration and that issue was not identified as a material issue prior to the QIC's reconsideration;
  - (2) When the ALJ determines that new evidence is material to a new issue identified after the QIC's reconsideration decision;
  - (3) When the party was unable to obtain the evidence before the QIC issued its reconsideration and the party submits evidence that it made reasonable attempts to obtain the evidence before the QIC issued its decision; and
  - (4) Where the evidence was submitted to the QIC or another contractor prior to the QIC issuing its decision.

- The Final Rule established new requirements for requests for ALJ hearing involving statistical sampling and extrapolation:
  - An appellant's request for ALJ hearing in a case involving statistical sampling and extrapolation must:
    - (1) Meet all regulatory content requirements for a Request for ALJ hearing for each sampled claim;
    - (2) Be filed for all appealed claims within 60 calendar days from the date the party receives the last reconsideration for the sampled claims (if they were not addressed by a single reconsideration); and
    - (3) Set forth the reasons the appellant disagrees with how the statistical sample and extrapolation was conducted.
  - If a request is incomplete, an appellant will be provided with an opportunity to cure and complete its request; if an appellant fails to complete its request in the timeframe specified by the ALJ, the appellant's request for ALJ hearing or review may be dismissed.

SENDING COPIES OF REQUESTS FOR ALJ HEARINGS TO ALL PARTIES 42 C.F.R. §405.1014

- Prior to the enactment of the Final Rule, appellants were required to send their requests for ALJ hearing to all other parties to the reconsideration or dismissal; if an appellant failed to provide copies to all other parties to the reconsideration or dismissal, the ALJ's 90-day adjudication timeframe was extended until all required copies were provided. The Final Rule contains 2 important clarifications to this requirement:
  - (1) The Final Rule amended the copy requirement such that appellants are now required to send copies of their requests for ALJ hearing only to the parties who were sent a copy of the QIC's reconsideration decision or dismissal;
  - (2) The Final Rule clarified HHS's position that, if additional materials submitted with a request are necessary to complete request, then such materials must be sent to the other parties as well (subject to HIPAA's limitations on disclosing personal information).
    - In commentary to the Final Rule, HHS specified its position that if a brief or position paper explaining the reasons the appellant disagrees with the QIC's reconsideration is submitted with the request, then such brief or position paper must be sent to the other parties.
    - On the other hand, if additional evidence is submitted (e.g., medical records) that generally is not required to complete a request for ALJ hearing, such evidence would not need to be sent to the other parties. Rather, the appellant could summarize such evidence to the other parties and provide it to them upon request.

SENDING COPIES OF REQUESTS FOR ALJ HEARINGS TO ALL PARTIES
42 C.F.R. §405.1014

- Compliance with the copy requirement can be established through:
  - (i) Certification on the Form OMHA-100 that a copy of the request is being sent to the other parties;
  - (ii) An indication, such as a copy or "cc" line, on a request for hearing that a copy of the request and any applicable attachments or enclosures are being sent to the other parties, including the name and address of the recipient;
  - (iii) An affidavit or certificate of service that identifies the name and address of the recipient and what was sent to the recipient; or
  - (iv) A mailing or shipping receipt that identifies the name and address of the recipient, and what was sent to the recipient.

- The Final Rule established the regulatory authority for ALJs to grant appellants the opportunity to cure appeal defects related to their failure to copy all parties in receipt of a reconsideration decision. If an appellant does not provide evidence that it submitted copies of its complete request for ALJ hearing to the other parties within a time frame specified by the ALJ, the ALJ may dismiss an appellant's request for ALJ hearing or review.

PLACE FOR A HEARING
42 C.F.R. §405.1020

- Prior to the enactment of the Final Rule, federal regulations made video-teleconference ("VTC") the default mode of hearing.
- The Final Rule amended the default mode of ALJ hearings to be telephone, rather than VTC, for appellants other than unrepresented beneficiary appellants.
  - For unrepresented beneficiary appellants, the default mode of ALJ hearings would remain VTC.
- The Final Rule allows for hearing by VTC or in person if good cause is shown. Examples of good cause include:
  - Where the ALJ or appellant raise an issue with a witness's credibility;
  - Where a party presents multiple witnesses, or the case presents complex issues (including appeals where a high volume of claims is at issue or involve a high dollar overpayment amount);
  - Where a party wishes to present visual or video evidence.

NOTICE OF HEARING / ISSUES PRESENTED
42 C.F.R. §§405.1022 AND 405.1032

- Prior to the enactment of the Final Rule, regulations required a notice of hearing (NOH) to set forth the specific issues to be decided during the ALJ hearing.
- Under the Final Rule, a specific issue statement is no longer required to be included in the NOH.
  - Rather, issues before the ALJ (or AA) in all cases will include all of the issues for the appealed matter that were brought out in the initial determination, redetermination or reconsideration *that were not decided entirely in a party's favor,* as well as any specific new issues that the ALJ may consider.
- HHS acknowledges that new issues may arise resulting from the participation of a CMS contractor and/or position papers submitted by a CMS contractor for the first time at the OMHA level.
- The ALJ or any party may raise a new issue relating to an appealed matter specified in the request for hearing; however, an ALJ may only consider a new issue, including a favorable portion of a determination on an appealed matter, if its resolution could have a material impact on the appealed matter and:
  - (1) There is new or material evidence that was not available or known at the time of the determination and that may result in a different conclusion, or
  - (2) The evidence that was considered clearly shows on its face that an obvious error was made.

HEARING PROCEDURES
42 C.F.R. §405.1030(B)

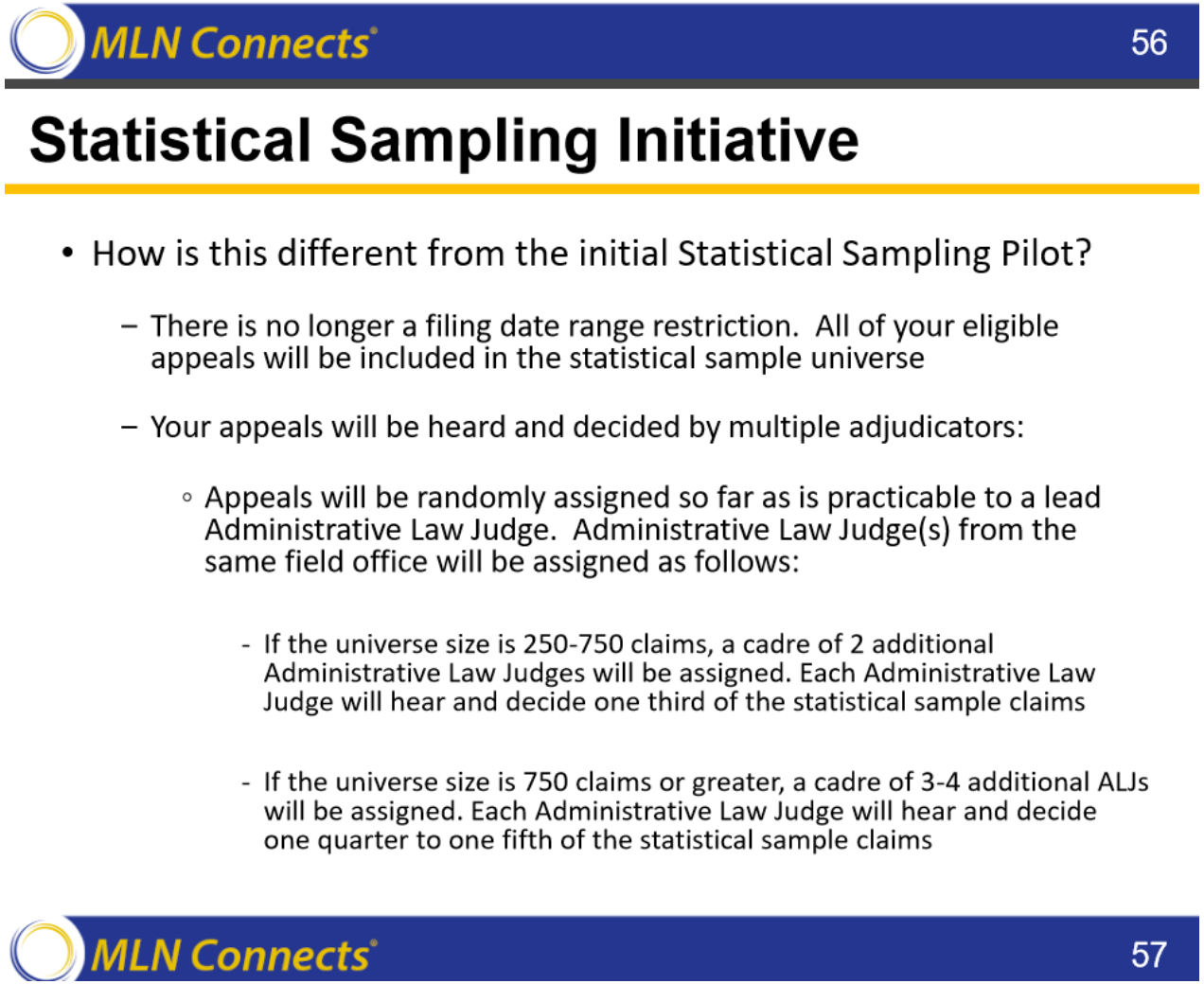
- In the Final Rule, HHS described scenarios where a party or representative impeded the ALJ from regulating the course of the ALJ hearing.
  - E.g., Where a party or representative continued to present testimony or argument on irrelevant issues or on a matter that the ALJ believes he or she has sufficient information to render a ruling or the ALJ has already ruled; and where a party or representative is uncooperative, disruptive or abusive during the hearing

- If an ALJ determines that a party or representative is presenting testimony and/or argument that is irrelevant, repetitive, or that relates to an issue that has been sufficiently developed or on which the ALJ already ruled, the ALJ may limit the testimony or argument. The ALJ **may, but is not required to**, provide the party or representative with an opportunity to submit additional written statements and affidavits, which must be submitted within the timeframe designated by the ALJ.

- If an ALJ determines that a party or representative is uncooperative, disruptive or abusive, after the ALJ has warned the party or representative to stop its negative behavior, the ALJ may excuse the party or representative from the hearing. If a party or representative is excused from a hearing, the ALJ **is required to** provide the excused party or representative with an opportunity to submit written statements and affidavits. The party or representative may request a recording of the hearing.

HOT TOPIC – REVISED STATISTICAL SAMPLING INITIATIVE

- Revisions to HHS' SSI:



WHEN DO YOU KNOW ITS TIME TO STOP APPEALING?

- Evaluation of appeals success by claim type
- Evaluation of payor contracts, coverage policies and other authorities, including (for Medicare) precedential Medicare Appeals Council decisions

QUESTIONS?

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