It Don't Mean A Thing If It Ain't Got Jurisdiction: Jurisdictional Principles And Issues For Appeals Before The PRRB And The Federal Courts

Session 29

March 26, 2021

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AMERICAN HEALTH LAW ASSOCIATION

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  - *This session does not represent the official position of the Department of Health and Human Services.*
  - *This session does not furnish legal advice regarding any specific case or situation*.

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They Advised Us To Jazz Up The Program

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Materials

Outline

Reference Material On The Web:

- Board Rules 2.0 issued on August 29, 2018 and posted on the web:
  - https://www.cms.gov/Regulations-and-Guidance/Review-Boards/PRRBReview/Downloads/PRRB-Rules-August-29-2018.pdf
- Alert 19 issued March 25, 2020 and posted on the web:
  - https://www.cms.gov/Regulations-and-Guidance/Review-Boards/PRRBReview/PRRB-Alerts
- CMS Ruling 1739-R issued August 17, 2020 and posted on the web:
  - https://www.cms.gov/files/document/cms-1739-r.pdf

Presentation Topics

Current Board Members

PRRB Jurisdiction Legal Authority

Lessons Learned In “The PRRB Zone”

Alert 19 / CMS Ruling 1739-R

Pomona Decision (Standard of Review)

Requirements For Federal Court Jurisdiction

- Law
- Recent Cases

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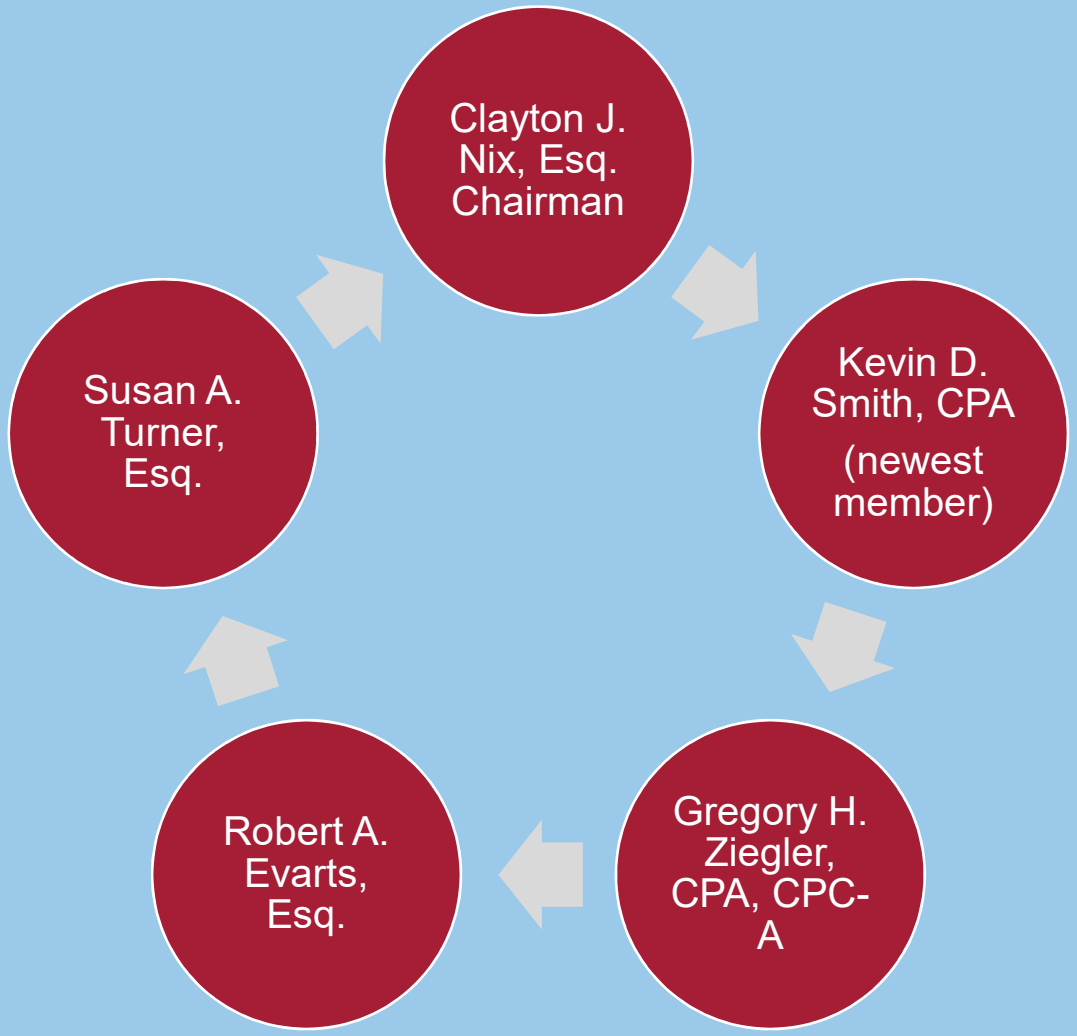
Meet The Current Board Members



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PRRB Jurisdictional Authority

42 U.S.C. § 1395oo(a)

42 C.F.R. § 405.1801 *et seq*.

Instructions: Rules 2.0 On PRRB Website (8/29/2018)

- ******Electronic Filing Via OH CDMS******

Series Of Alerts (20) Published on PRRB Website

PRRB, CMS Admin. and Judicial Case Law

PRRB jurisdictional decisions published quarterly commencing with August 2013.

STATUTORY REQUIREMENTS FOR PRRB JURISDICTION

42 U.S.C. § 1395oo(a)

- Dissatisfaction With Final Payment Determination
  - By Medicare Administrative Contractor or
    By Secretary
- Amount in Controversy $10,000 or more ($50,00 for group appeal)
- File Request Within 180 Days of Receipt of Determination
  - Receipt assumed five days after date on determination

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“The PRRB Zone”

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Final Determination

Lesson Learned:

Final Payment Determination For PRRB Jurisdictional Purposes

--NPR; Revised NPR; "Delayed" NPR

--Federal Register Final Rule

--Payment / Rate Determinations (E.g., ESRD exception request; Quality Reporting Program determination)

Not Final Determination

--MAC denial of request for reopening or request to amend cost report

--Notice of GME / IME FTE Caps for new teaching hospital

--PRRB Remand(?)

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Dismissal

Lesson Learned

If the Provider gives the MAC the opportunity to challenge jurisdiction, the MAC will do so, and at any time.

If the Provider gives the Board the opportunity to dismiss for lack of jurisdiction, the Board will do so.

"Dismiss(al)" appears at least 20 times in the Board Rules. ("Dismissal" appears once in Fed Rules Civil Procedure)

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The Dissatisfaction Requirement

Dissatisfaction With Final Payment Determination

- By Medicare Administrative Contractor or
- By CMS/Secretary

- The most heavily litigated jurisdictional element.

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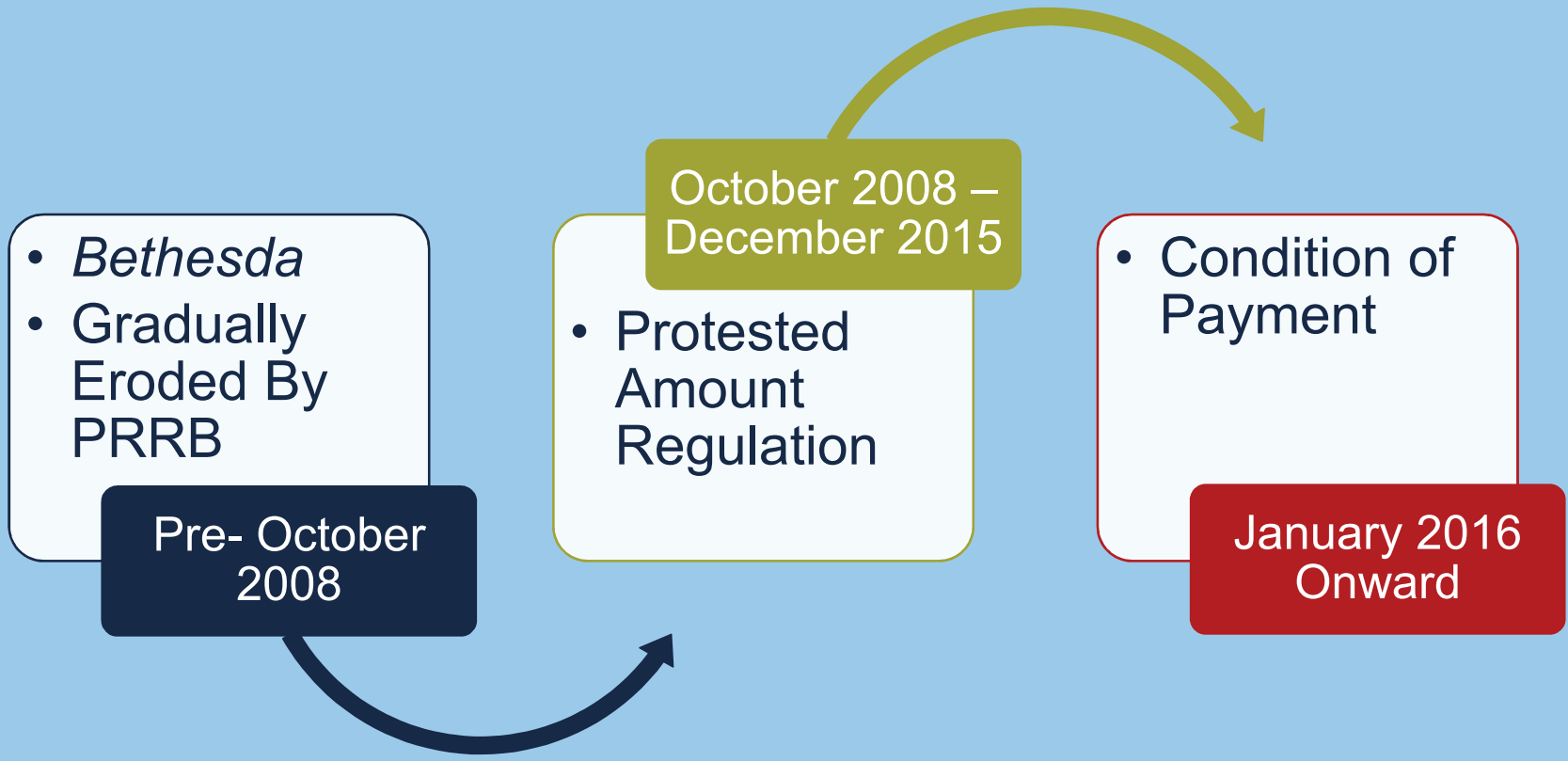
Lesson Learned: Dissatisfaction Means Different Things At Different Times For Different Purposes (Although the Statute Has No Changed)



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Bethesda: Pre-2008

Self Disallowance: Supreme Court Interpretation

"[t]he only limitation prescribed by Congress is that the matter must have been 'covered by such cost report,' that is, a cost or expense that was incurred within the period for which the cost report was filed, even if such cost or expense was not expressly claimed."

- *Bethesda Hospital Ass'n v. Bowen*, 485 U.S. 399, 405 (1988)

The Protested Amount Regulation: 405.1835(a)(1)(ii) 10/1/2008-1/1/2016

Effective FYE's Ending On/After 12/31/2008: Protested amount required if do not claim a payment item.

The MAC routinely challenges the PRRB's jurisdiction over an appeal for which there is no audit adjustment if the provider did not file a protested amount.

PRRB devised the "practical impediments" principle regarding unclaimed eligible days.

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Challenge to Protested Amount: Delayed NPR

Provider has right to appeal during the 180 days of the first anniversary of filing a complete cost report ("Delayed NPR")

42 USC 1395oo(a)(1)(B) and (3)

<u>Dissatisfaction Not Required For Delayed NPR Appeal</u>

Injunction Issued: Charleston Area Med. Ctr. v Sebelius, D.D.C., No. 13-766 (August 6, 2014).

2015 Technical Correction

42 C.F.R. 405.1835(c)(1)

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Challenge to Protested Amount: Delayed NPR

2015 Final IPPS Rule Acquiesced:

". . . [B]ecause we would require an appropriate cost report claim in proposed § 413.24(j), it is reasonable to eliminate the Board jurisdiction requirement in existing §§ 405.1835(a)(1) and 405.1840(b)(3) of an appropriate cost report claim. We note that once this amendment to the Board appeals regulations becomes effective, this proposal will facilitate an orderly end to any litigation regarding the Board jurisdiction requirement of an appropriate cost report claim."

Challenge to Protested Amount: Regulatory Challenge

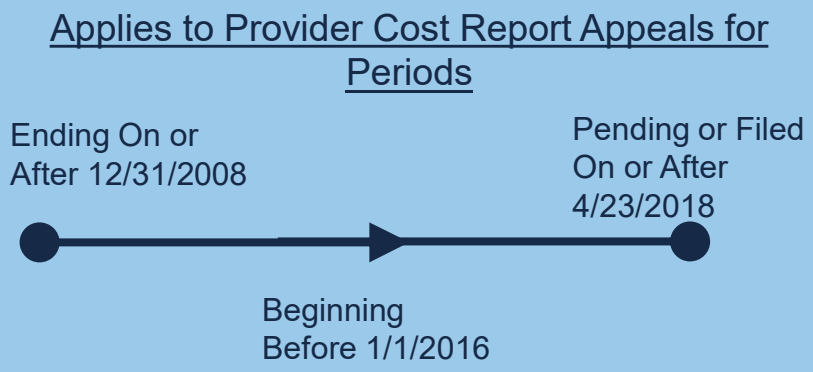
2016 D.C. District Court Ruling

The Court held that a protested item is not required when a provider challenges a regulation

- *Banner Heart Hospital et al. v. Burwell*, No. 14-1195-APM. (Outlier regulation)
- Supreme Court decision in *Bethesda* applied.
  - DHHS appealed to DC Circuit but subsequently withdrew the appeal.
  - Case remanded to PRRB for jurisdiction determination.

CMS Ruling 1727-R Issued 4/23/2018

CMS announced that it would follow the 2016 decision in *Banner Heart Hospital v. Burwell* that the 2008 "self-disallowance regulation" for establishing jurisdiction for purposes of contractor PRRB appeals does not apply to appeals challenging a payment regulation or other policy that the Medicare contractor cannot address. 201 F. Supp. 3d 131 (D.D.C. 2016).



In practice the MAC seeks to narrow the scope to challenge of a regulation.

KRM article on this topic available upon request.

Adopted Bethesda and Banner Heart Hospital.

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Amended Cost Report and Appeals Rules: 1/1/2016

Effective for Cost Reporting Periods Beginning On or After 1/1/2016

Amended Cost Report Rule: 42 CFR § 413.24

*"Claim or Explain" **

***The protested amount is a condition of payment.*

*(copyright © 2016 Ken Marcus)

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Amended Cost Report and Appeals Rules: Protested Amount = Condition of Payment

Amended Appeals Rules: "From *Bethesda* to Gotcha" *(copyright © 2016 Ken Marcus)*

42 C.F.R. § 405.1835

Amended to delete the jurisdictional requirement that a provider must include a protested amount in order to self-disallow a reimbursement item.

42 C.F.R. § 405.1873

New Section

Prescribes in exacting detail the PRRB's review of whether the Provider complied with the requirements of 413.24(j).

42 C.F.R. § 405.187(f)

The CMS Administrator's review of the decision of the PRRB focusses on the cost report.

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Dissatisfaction With Revised NPR

Lesson Learned:

RNPR is ***issue specific***: Board jurisdiction limited to adjustments. 42 C.F.R. 405.1889(b)(2)

"Any matter that is not specifically revised (including any matter that was reopened but not revised) may not be considered in any appeal of the revised determination or decision."

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Dissatisfaction: What Did The Provider Intend To Appeal And Did The Provider Appeal It?

Lesson Learned:

Terminology changes over time, e.g., "Dual Eligible Days" may mean something different in 2004 than in 2020.

DSH has evolved into several separate components subject to appeal.

Issue identification must be specific.

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Dissatisfaction: Gotcha!

Lesson Learned:

Did the Provider appeal only one component of a multi-component issue?

E.g., IME FTE count but not available beds?

E.g., Did the Provider appeal each year impacted (GME/IME FTE Caps Floating 3 Year Average).

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Dissatisfaction: Can I Avoid The Time, Effort and Cost of an Appeal By Relying On A Reopening?

Lesson Learned:

Reopening discretion is vested in the MAC and is not subject to judicial review. (*Your Home*, 525 U.S. 449 (1999))

But Board Rules permit withdrawal of all or part of an appeal in reliance on a proposed reopening or administrative resolution. See Rule 47.2.

And appeal can be filed and simultaneously withdrawn in reliance on a reopening. See Rule 47.2.3.

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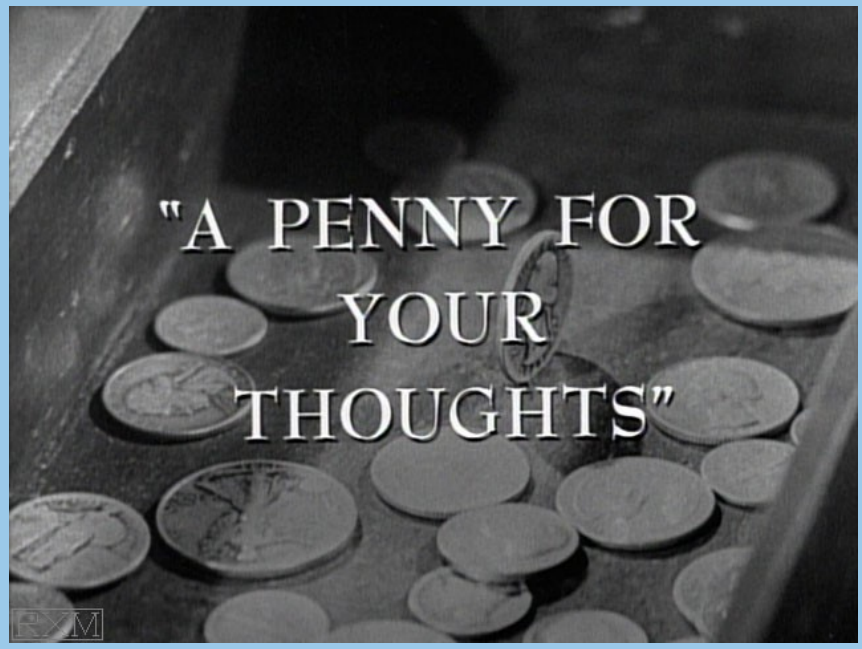
Amount In Controversy

- Amount in Controversy $10,000 or more ($50,00 for group appeal)
- **Lesson Learned**:
  - Contractor hearing available for $1K to $10K (but why?!)
  - Can fall below $10K if issues are settled, transferred or abandoned. 42 CFR § 405.1839(c)(5)(A).
  - But the Board can make a more accurate assessment. Id. (B)

Consider Cost / Benefit



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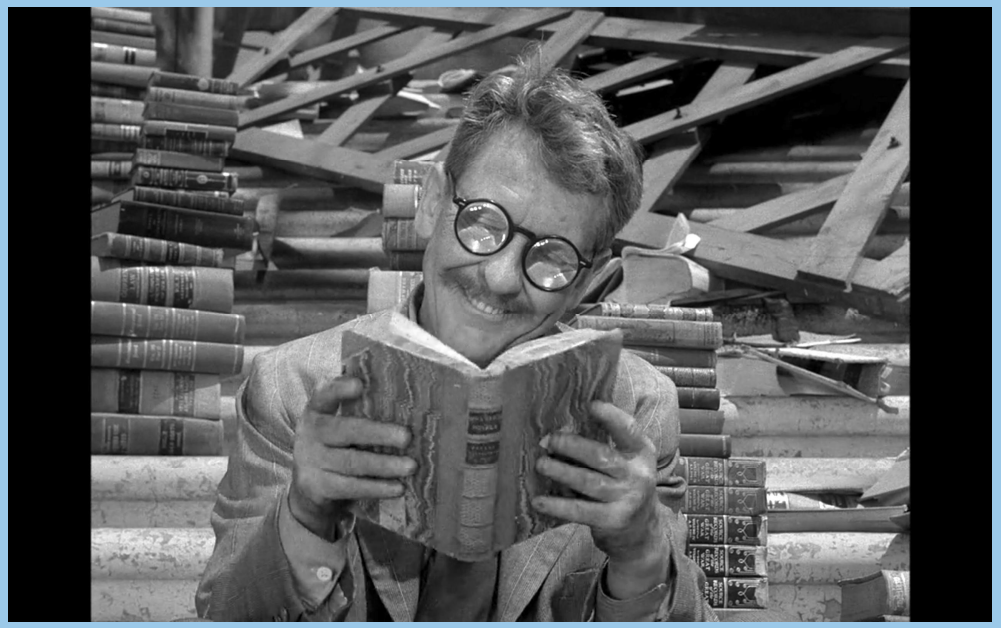
Timely Filing Within 180 Days

Lesson learned:

- Five day rule for receipt of final determination (provider can rebut, *not MAC*) **42 C.F.R. §405.1801(a)**
- Five day rule does not apply to appeal from Fed. Reg.
- *Must be TIMELY RECEIVED by the Board.*
  - *Electronic Filing Helps!*



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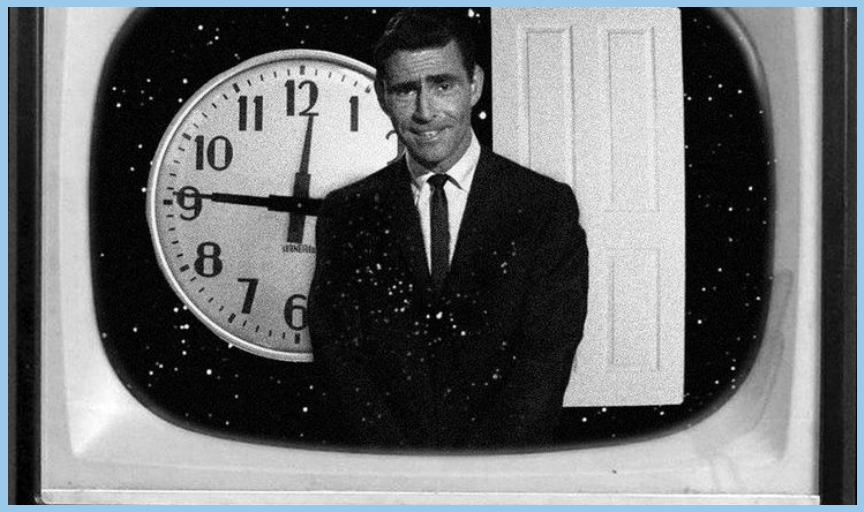
Timely Filing Within 180 Days

Lesson learned:

- Within 185 days of NPR
  - Add issue within 60 days
- Within 185 days of RNPR
  - Add issue within 60 days
- Within 180 days one year after date cost report accepted*
- Within 180 days of final rule publication in Fed Reg.*
- Within 181 days-3 years for good cause.*
- *Can issue be added within 60 days?



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Timely Filing Within 180 Days

Lesson learned:

- "Good Cause Exception"
- 42 CFR § 405.1836
  - 181 days-3 years
  - "Good cause" needs to be good: Extraordinary circumstances beyond provider's control (Natural or other catastrophe, fire, strike)
  - Rarely granted.
  - Decision not subject to judicial review per paragraph (e)(4) of the regulation (But see *Oakland Phys. Med. Ctr. v. Azar,* 330 F. Supp. 3d 391 (D.D.C. 2018))

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Timely Filing Within 180 Days

Lesson learned:

- It's not "jurisdictional"
  - *Sebelius v. Auburn Regional Medical Cen*ter, 568 U.S. 145 (2013)
- Don't count on equitable tolling.
  - *Auburn*.
- And don't count on the Board finding "good cause" for a late filing.

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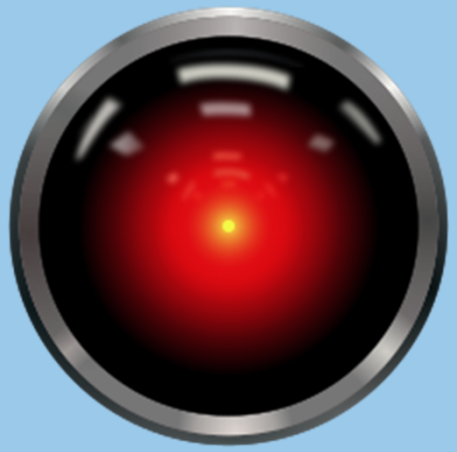
Timely Filing Via OH CDMS: 11:59 PM Eastern (But stay alert to down times!)

Lesson learned



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Provider Penalty For Missing Deadline

Lesson learned:

42 C.F.R. § 405.1868(b)

If a provider fails to meet a filing deadline or other requirement established by the Board in a rule or order, the Board may—

(1) ***Dismiss the appeal with prejudice***;

(2) Issue an order requiring the provider to show cause why the Board should not dismiss the appeal; or

(3) Take any other remedial action it considers appropriate.

Review of decisions indicates dismissal is sanction of choice.

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MAC Penalty For Missing Deadline

Lesson learned:

42 C.F.R. § 405.1868(c)

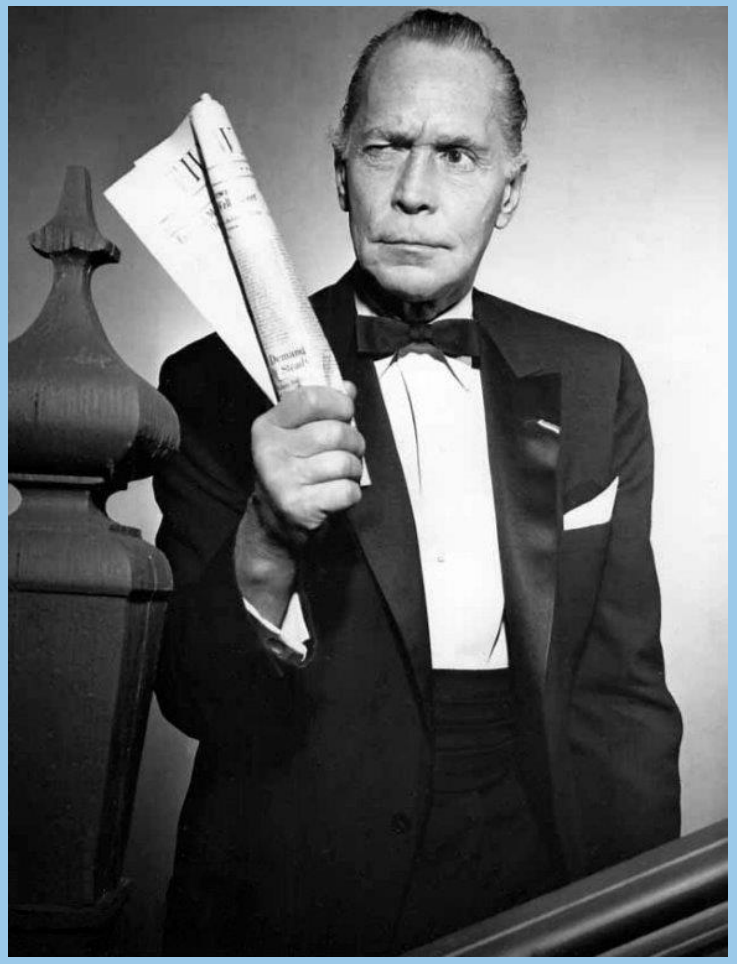
If a contractor fails to meet a filing deadline or other requirement established by the Board, the Board may -

(1) Take other actions that it considers appropriate, such as -

(i) Issuing a decision based on the written record submitted to that point; or

(ii) Issuing a written notice to CMS describing the contractor's actions and requesting that CMS take appropriate action, such as review of the contractor's compliance with the contractual requirements of §§ 421.120, 421.122, and 421.124 of this chapter; and

(2) ***Not use its authority to take an action such as, a sanction, reversing or modifying the contractor's or Secretary's determination for the cost reporting period under appeal, or ruling against the contractor on a disputed issue of law or fact in the appeal.***



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PRACTICAL PRRB POINTERS

Lesson learned:

Do Not Miss The 180-Day Appeal Deadline

Comply With All Other Deadlines

DO NOT EVER FAIL TO RESPOND TO A PRRB LETTER

Never Rely On Ordinary First Class Mail

Use Caution In Placing Correspondence Regarding Two Different Appeals In The Same Envelope

Get To Know And Cooperate With PRRB/MAC/FSS Staff

If In Doubt Confer With PRRB Staff

- But Confirm In Writing

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PRACTICAL PRRB POINTERS

Lesson learned:

Seek Settlement (Note Mediation Is encouraged but difficult to arrange)

Narrow Issues For Appeal

Stipulate To Facts

- **Caution**: In federal court, DHHS may repudiate a stipulation.

Request A Hearing

- If left to the PRRB, the hearing may not be scheduled for years

Conducting Hearing By Phone (or Zoom) If No Facts In Dispute Yields Substantial Savings

Request EJR To Bypass Lengthy PRRB Process

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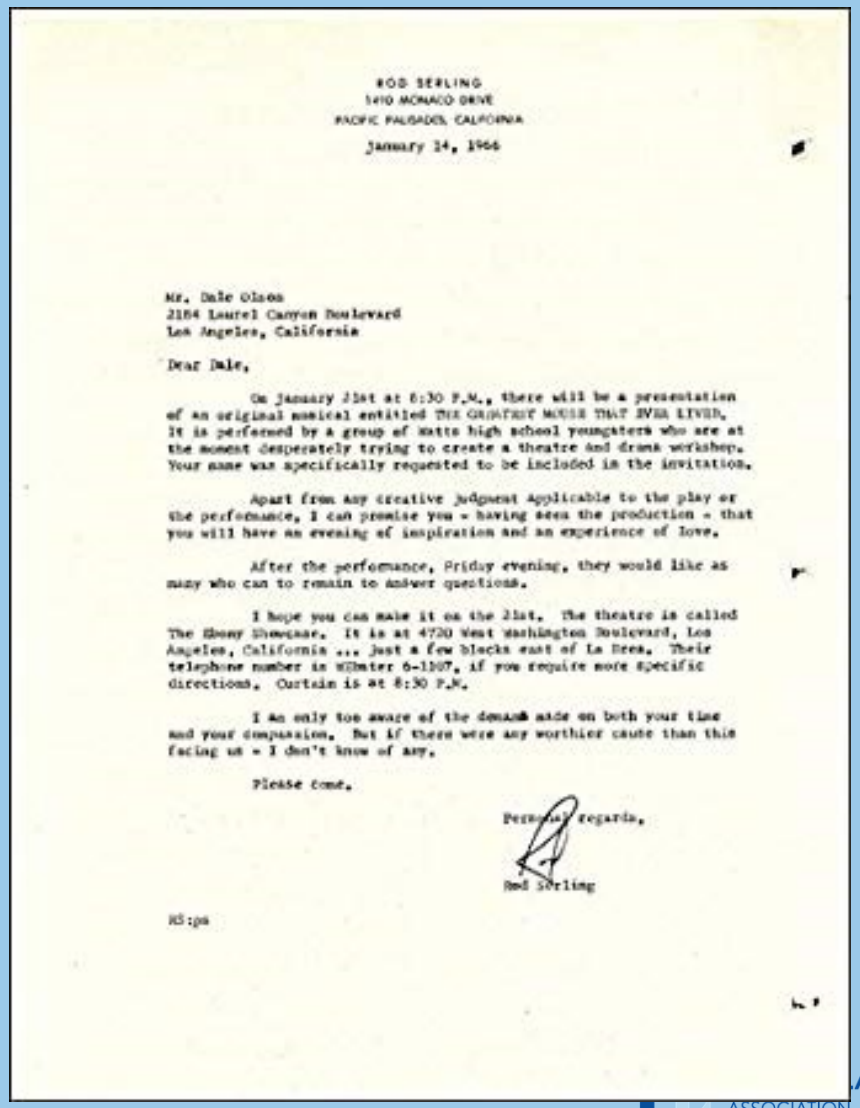
Representation Letter (Rule 5.4)

Lesson learned

A representation letter is required whether designating an external or internal representative.

The letter designating the representative must:

- be on the provider's letterhead,
- be signed by an authorizing official of the provider or parent organization,
- reflect the provider's name, number, and fiscal year under appeal, and
- **not** be issue specific unless it is for participation in a group appeal in which there is only one issue permitted to be raised.



ROD SERLING
1410 MONACO DRIVE
PACIFIC PALISADES, CALIFORNIA

January 24, 1966

Mr. Dale Olson
2184 Laurel Canyon Boulevard
Los Angeles, California

Dear Dale,

On January 31st at 8:30 P.M., there will be a presentation of an original musical entitled THE GREATEST MOUSE THAT EVER LIVED. It is performed by a group of Watts high school youngsters who are at the moment desperately trying to create a theatre and drama workshop. Your name was specifically requested to be included in the invitation.

Apart from any creative judgment applicable to the play or the performance, I can promise you - having seen the production - that you will have an evening of inspiration and an experience of love.

After the performance, Friday evening, they would like as many who can to remain to answer questions.

I hope you can make it on the 31st. The theatre is called The Ebony Showcase. It is at 4720 West Washington Boulevard, Los Angeles, California ... just a few blocks east of La Brea. Their telephone number is WEbster 6-1107, if you require more specific directions. Curtain is at 8:30 P.M.

I am only too aware of the demands made on both your time and your compassion. But if there were any worthier cause than this facing us - I don't know of any.

Please come.

Personal regards,

Rod Serling

RS:ps

COVID 19 → Alert 19

Issued In Response To Pandemic

Board Deadlines Friday March 13, 2020 and Forward

- "Board Set Deadlines" are suspended
  - E.g., Preliminary Position Papers, Final Position Papers, Schedules of Providers, Witness Lists, Case Status reports
- "Board Set Deadlines" Does Not Include deadline for filing appeal or adding issues to an appeal.
  - *Note Board case-specific letters may also state that a deadline is not suspended, such as a specific hearing date and corresponding filing deadlines*.
- EJR Request Process Is Delayed
  - PRRB Staff working remotely; delay due to difficulty in accessing the hard copy Schedule of Providers

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CMS Ruling 1739-R

Issued August 17, 2020

Declares as moot appeal of the DSH Part C Issue

Board instructed to determine if it has jurisdiction over the DSH Part C Issue, and if so to remand to the MAC

The remand to the MAC is for processing under a yet to be finalized retroactive rule regarding DSH Part C payment.

Apparent intent is to close pipeline of cases being filed in the DC District Court challenging the DSH Part C Payment

- *Note that the PRRB has denied EJR in cases challenging the DSH Part C Payment in reliance on Alert 19 (inability to make jurisdictional determination due to lack of access to hard copy), but nonetheless has made the identical jurisdictional determination under the Ruling and remanded to the MAC.*

Challenges to the Ruling are mounting in the DC District Court.

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CMS Administrator Review

PRRB Decision Subject To Review By CMS Administrator

- Approximately 90% of provider-favorable decisions are reviewed and reversed.
- To decide to have a PRRB hearing is to decide to go to federal court. (*I.e.*, the case is unlikely to be resolved at the PRRB level of appeal.)

Following Exhaustion Of Administrative Appeals Process: Federal Court

- Note: Exhaustion of administrative appeals process is mandatory. But a provider is not required to request/receive Administrator review as a prerequisite to proceed to federal court.

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PRRB Standard Of Review

The PRRB's decision must be supported by substantial evidence. 5 USC § 706.

Pomona Valley Hospital Medical Center v. Azar, No. 18-2763 (ABJ) (9/30/2020)

- Accuracy of DSH SSI data in dispute
- At hearing MAC provided no testimony or evidence; criticized Provider's evidence and Board decision based on MAC's criticism.

"But the question before the Court is not whether plaintiff presented sufficient quantifiable data to prove that CMS's calculation was flawed, or whether plaintiff had ascertained the reasons for the discrepancies. ***The question is whether upon review of the entire record, there was substantial evidence to support the Board's decision*** that plaintiff's SSI fraction had been properly determined by CMS."

FEDERAL COURT JURISDICTION

42 U.S.C. § 1395oo(f)(1)

Providers shall have the right to obtain judicial review of any final decision of the Board, or of any reversal, affirmance, or modification by the Secretary, by a civil action commenced within 60 days of the date on which notice of any final decision by the Board or of any reversal, affirmance, or modification by the Secretary is received.

FEDERAL COURT JURISDICTION

42 U.S.C. 1395oo(f)(1)

The federal court possesses jurisdiction over a final decision of the Secretary of HHS.

- PRRB (or CMS Administrator Decision) on the merits
- PRRB decision dismissing case in its entirety
- PRRB decision ordering expedited judicial review

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REQUIREMENTS FOR FEDERAL COURT JURISDICTION

Final decision requires *exhaustion of administrative remedies*

Shalala v Illinois Council on Long Term Care, Inc., 529 U.S. 1 (2000)

- 42 U.S.C. § 405(h), as incorporated by 42 U.S.C. § 1395ii, barred federal question jurisdiction over actions brought pursuant to 28 U.S.C. § 1331.
- Respondent could proceed through the special review channel created by the Medicare statutes so applying these provisions did not deny judicial review as a practical matter.

FEDERAL COURT JURISDICTION

Based on *case law* certain actions are not final decisions subject to judicial review. *E.g.*:

MAC denial of reopening request is not a final decision.

- *Your Home Visiting Nurse Services v. Shalala*, 524 U.S. 449 (1999)

Challenge to PRRB remand under CMS Ruling 1498-R not a final decision.

- *Empire Health Foundation et al. v Burwell*, No. 15-2251 (JEB) (9/19/2016)
  - But following remand the Providers appealed to the PRRB from a revised NPR; the Board denied jurisdiction over items not adjusted in the RNPR, the Providers filed a complaint but the case was settled.

FEDERAL COURT JURISDICTION

Based on *statute* certain actions are not final decisions subject to administrative or judicial review. *E.g.*:

Low Income Percentage

- 42 U.S.C. § 1395ww(j)(8)(B)
- *Mercy Hospital, Inc. v. Azar*, No. 16-5268 (D.C. Cir. 6/8/2018)

ACA DSH Uncompensated Care Data

- 42 U.S.C. § 1395ww(r)(3)
  - *Florida Health Scis. Ctr., Inc. v. Burwell*, 830 F.3d 515 (D.C. Cir. 2016) – challenge to data used in estimates
  - DCH Reg'l Med. Ctr. v. Azar, 925 F.3d 503 (D.C. Cir. 2019) – challenge to methodology
  - *Scranton Quincy Hosp. Co. v. Azar*, 2021 WL 65449 (D.D.C. 1/7/2021) – challenge to application

FEDERAL COURT JURISDICTION

The Medicare statute has several other statutory preclusions of judicial and administrative review, e.g.

TMA Act adjustments to IPPS:

Fresno Cmty. Hosp. & Med. Ctr. v. Cochran, No. 19-5254 (D.C. Cir. Feb. 9, 2021).

Compare American Hospital Association v. Azar, 964 F.3d 1230 (D.C. Cir. 2020) ("site neutral" OPPS adjustments: judicial review available where preclusion question merged with merits question).

FEDERAL COURT JURISDICTION

Based on *regulation* certain actions are not final decisions subject to judicial review. *E.g.*:

CMS Administrator review of Medicare Geographic Classification Review Board

- 1395ww(d)(10)(C)(iii)(II), 42 C.F.R.412.278(f)(4)

PRRB decision denying good cause exception for late filing

- 42 C.F.R. § 405.1836(e)(4)

FEDERAL COURT JURISDICTION: GOOD CAUSE EXCEPTION TO 180 DAY DEADLINE

42 C.F.R. § 405.1836

--"[The provider demonstrates in writing it could not reasonably be expected to file timely due to **extraordinary circumstances beyond its control** (such as a natural or other catastrophe, fire, or strike), and the provider's written request for an extension is received by the Board within a reasonable time (as determined by the Board under the circumstances)"

--CMS: "**We have not defined all the 'extraordinary circumstances**' that the provider can rely upon to satisfy a 'good cause' extension. Therefore the Board has the discretion to weigh the factual scenarios presented by a provider and make its decision accordingly." 73 Fed. Reg. 30207 (May 23, 2008).

--***Review of decisions indicates that the PRRB strictly interprets the regulation.***

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FEDERAL COURT JURISDICTION: GOOD CAUSE EXCEPTION TO 180 DAY DEADLINE

Validity Of Good Cause Exception Regulation Upheld by Supreme Court in *Sebelius v. Auburn Regional Medical Center*, 133 S.Ct. 817 (January 22, 2013).

But, Per *Auburn, Equitable* Tolling Is Not Available

FEDERAL COURT JURISDICTION: GOOD CAUSE EXCEPTION TO 180 DAY DEADLINE

The regulation precludes judicial review of the PRRB's denial of a good cause exception:

"A finding by the Board ... that the provider did or did not demonstrate good cause for extending the time for requesting a Board hearing is not subject to judicial review."

- 42 C.F.R. § 405.1836(e)(4).

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FEDERAL COURT JURISDICTION: GOOD CAUSE EXCEPTION TO 180 DAY DEADLINE

"A denial of a good-cause extension is, by any definition, a 'decision.' It also is a decision 'of the Board.' And, in this case, the Board's decision is 'final.' The statute provides: 'A decision of the Board *shall be final* unless the Secretary, on his own motion, and within 60 days after the provider of services is notified of the Board's decision, reverses, affirms, or modifies the Board's decision.' 42 U.S.C. § 1395*oo*(f)(1) (emphasis added). The Secretary took no action on the Board's denial of Plaintiff's extension request and therefore the Board's decision became 'final' 60 days after the Board made the decision."

- *Oakland Physicians Medical Center v. Azar,* 330 F.Supp 3d 391, 400 (D.D.C. 2018)

FEDERAL COURT JURISDICTION

Expedited Judicial Review (EJR)

- PRRB Is Bound By Statute, Regulation and CMS Rulings
- Although PRRB May Enjoy Procedural Jurisdiction, It May Lack Authority Over Issue In Dispute
- Provider Can Request, Or PRRB On Own Motion, Can Determine That PRRB Lacks Authority
- If Provider Requests EJR, PRRB Has 30 Days To Respond To A Complete Request

42 U.S.C. § 1395oo(f)(1); 42 C.F.R. § 405.1842

Judicial Review of PRRB EJR Order

- *Allina v. Price (Allina II),* D.C. Cir. 16-5255 (7/25/2017)
- *Clarian Health West v Hargan,* D.C. Cir. 16-5307 (12/26/2017)

The Secretary cannot challenge the PRRB's EJR decision in court.

The CMS Administrator can only review PRRB's *jurisdictional* determination.

Judicial Review of PRRB EJR Order

Bayshore Cmty. Hosp. v. Hargan, No. 16-cv-2353, 2017 WL 4857426 (D.D.C. Oct. 25, 2017) –Appeal of outlier payment, dismissed by the PRRB for failure to include protested amounts.

--Secretary sought remand for PRRB to take jurisdiction and court denied it, but also denied plaintiff's motion to vacate the regulation.)

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Judicial Review of PRRB EJR Order

Bayshore Cmty. Hosp II, 16-2353 (D.D.C. 9/6/2018

- Court reversed prior decision and remanded to PRRB.
  - Secretary offered a "more fulsome explanation" of the PRRB's limited authority regarding the self disallowance regulation
  - CMS 1727-R Issued
  - *Billings Clinic v Azar (*D.D.C. 17-5006 8/10/2018): Identified potential complications of a case arriving in court without proper PRRB certification where PRRB lacked jurisdiction, but found that PRRB had jurisdiction for all of the Plaintiffs albeit not all years on appeal.
  - [Add Clarian Health West]

Judicial Review of PRRB EJR Order

Clarian Health West v. Azar, 14-cv-339 (KBJ) (D.D.C. 11/30/2020) – Court determines that PRRB had jurisdiction.

Proper remedy is remand to the Board so the Board can grant EJR, not retention of jurisdiction by district court.

Judicial Review of PRRB Discretionary Jurisdiction Decision

Memorial Herman Memorial City Medical Center v. Burwell, S.D. Tx. (17-0065 and 18-0147) (8/28/2018)

- Inadvertently omitted claim (See *St. Vincent*, supra)
- Plaintiff claimed received erroneous MAC guidance.
- Court found PRRB decision that fault was solely provider's was not supported by substantial evidence and remanded to the Secretary.

  - ***St. Vincent Indianapolis Hosp. v. Sebelius***, 134 F. Supp. 3d 238 (D.D.C. 2015).

Judicial Review of PRRB Dismissals

Akron Gen'l Hosp. v. Azar, 2021 WL 672348 (D.C. Cir., 1/29/2021)

PRRB remanded challenge to SSI fraction, dismissed appeals of other DSH sub-issues as untimely added and abandoned.

Court affirms district court dismissal of remand issue.

Court upholds validity of requirement that providers add issues to individual appeals within sixty days after appeal filed: regulation authorized by 42 U.S.C. 1395oo(e).

Court affirms PRRB dismissal of untimely added issue.

Allina: Kisor

Two 2019 Supreme Court Decisions:

- *Allina II:* Notice and Comment
- *Kisor: Auer* Deference

THE *ALLINA* LITIGATION REGARDING DSH PART C DAYS

- Medicare Part C:
  - Medicare Advantage.
  - Established by Balanced Budget Act of 1997
  - Managed care. (*E.g.*, Kaiser)
  - CMS pays the managed care plan, which provides or arranges for the provision of services.
- For most providers if Part C days are *removed* from the DSH Medicare Fraction, and if Part C days also eligible for Medicaid are *added* to the DSH Medicaid fraction, the DSH adjustment will be increased.
- The *Allina* litigation has addressed this issue.

THE *ALLINA* LITIGATION OVERVIEW

Allina I

Succeeded in obtaining decision invalidating the 2004 regulation but DC Circuit remanded for an adjudication. CMS upheld its position upon adjudication.

Allina III

- Appealed the CMS decision following adjudication.
- Court has ordered remand, motion to modify remand order pending.

Allina II

- Appealed 2012 DSH Part C Days
- Court granted DHHS motion for summary judgment.No.14-0415(GK). Held rule was "interpretive," not subject to notice and comment rule making requirements.
- Provider prevailed on appeal before DC Circuit. No.16-5255, Petition for Rehearing Denied 11/29/2017.
- ***Remanded to the agency.***

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ALLINA II

Allina II

Supreme Court Granted Certiorari For This Issue:

Does the Medicare Act, 42 USC §1395hh, provide an exception to notice and comment rule making for an interpretive rule?

- Note: Administrative Procedure Act contains an exception for an interpretive rule.

Hearing 1/15/2019

Decision 6/3/2019

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ALLINA II

A 7–1 decision (Justice Kavanaugh was recused) requiring the Centers for Medicare & Medicaid Services (CMS) to follow notice and comment rulemaking when adopting a "statement of policy" that establishes or changes a "substantive legal standard."

ALLINA II

- The CMS policy resulted in the reduction of Medicare DSH payments for hospitals for years prior to FY 2013, when the agency furnished notice and comment.
- As did the DC Circuit, the Supreme Court rejected the government's argument that the Medicare Act rulemaking requirement in 42 USC § 1395hh(a)(2) implicitly incorporated a similar interpretive rule exception permitting such a policy.

ALLINA II

- The plain language of 42 USC 1395hh requires notice and comment for any "rule, requirement, or other statement of policy…" that establishes or changes a "substantive legal standard."
- The Supreme Court focused on the phrase "substantive legal standard." It distinguished that phrase, apparently unused anywhere else in the United States Code, from the APA definition of substantive rule.

ALLINA II

What constitutes an agency promulgation that establishes or changes a "substantive legal standard"?

In *Allina II* a change to the Medicare DSH reimbursement formula impacting $3–$4 billion over a nine-year period is *substantive*

But there may be little to glean beyond that. The Court did not go so far as to establish any guidance beyond the context of the case, plainly noting, "Other questions about the statute's meaning can await other cases."

ALLINA II

The practical impact of the Supreme Court's decision

- CMS' argument is that while the Supreme Court found that there was not a validly promulgated regulation to support the CMS DSH Part C policy, neither is there a validly promulgated regulation to support the Providers' position.
- *Allina II* has been remanded without imposing any requirements or timeframes on CMS and without any status reports to the Court.
- A remand order has been issued in *Allina III* but the Providers are requesting modification to clarify that the Supreme Court vacated the prior policy.

ALLINA II

Scores of cases have been filed in the DC District Court in anticipation of the Supreme Court *Allina II* decision.

The Court granted the motion of CMS to consolidate all of the cases with *Albert Einstein Healthcare Network v Azar*.

CMS has moved for a remand similar to the remand in *Allina II* and *Allina III* which has been opposed and regarding which the Court has not issued its decision.

Thus: The story has not ended.

ALLINA II: Challenge To PRRB Jurisdictional Decision

Banner Univ. Med. Ctr. Phoenix Campus, et al. v. Azar, No. 19-cv-3788-JEB (D.D.C., filed Dec. 20, 2019).

- PRRB dismissed where Provider did not first add issue to its individual appeal and then transfer to a group appeal during the 60-day period to add an issue to an already filed appeal.
- According to the PRRB:
  - A provider may appeal within 180 days of its NPR through either an individual or a group appeal
  - A provider may add an issue to its pending individual appeal within 60 days following expiration of the 180-day deadline.
  - But the provider many not join a group appeal within 60 days following expiration of the 180-day deadline without first adding the issue to the group appeal.
- Plaintiffs allege PRRB Rules invalid for failure to comply with notice and comment rule making requirements.

Kisor v. Wilkie, *Secretary of Veterans Affairs*

Judicial Deference

- In several leading Medicare appeals over the years, such as *Thomas Jefferson* and *Guernsey Memorial Hospital*, the Courts have granted deference to CMS interpretation of regulations.
- If the court finds ambiguity, rather than being required to choose between competing reasonable interpretations, the court defers to the agency's reasonable interpretation.
- This principle has become known as "*Auer* Deference" (or "*Seminole Rock* Deference").

Kisor v. Wilkie, *Secretary of Veterans Affairs*

- The Supreme Court granted certiorari in *Kisor v. Wilkie*, *Secretary of Veterans Affairs* to decide whether to overrule the "*Auer* Deference" principle.
- At issue in *Kisor* was a Veterans Administration regulation regarding the effective date of an application for disability benefits related to post-traumatic stress disorder.
- The application was initially denied, but then granted upon reopening.
- The VA's interpretation of the applicable regulation was that the benefits would commence as of the date of the approval of the reopening, not the date of the original application.
- The Court of Appeals for Veteran Claims and the Federal Circuit affirmed the VA decision based on *Auer* Deference

Kisor v. Wilkie, *Secretary of Veterans Affairs*

- The Supreme Court in *Kisor* was presented with the opportunity to overrule *Auer*.
- The Court, however, declined to do so in reliance on " a presumption that Congress would generally want the agency to play the primary role in resolving regulatory ambiguities," which the Court discussed in some detail.
- But the Court recognized that Auer deference is subject to limitations:
  - **"deference can arise only if a regulation is genuinely ambiguous. And when we use that term, we mean it—genuinely ambiguous, even after a court has resorted to all the standard tools of interpretation"**

Kisor v. Wilkie, *Secretary of Veterans Affairs*

- Several Steps Must Be Completed Before Granting Deference
- A reviewing court must first determine whether ambiguity exists and must apply "traditional tools" of construction to interpret the regulation on its face
  - If uncertainty does not exist, there is no plausible reason for deference. … [I]f the law gives an answer—if there is only one reasonable construction of a regulation—then a court has no business deferring to any other reading, no matter how much the agency insists it would make more sense.
- Only if genuine ambiguity exists is deference to be granted.
  - The must determine whether the proffered interpretation of the agency is "reasonable." *Id*.

Kisor v. Wilkie, *Secretary of Veterans Affairs*

- If those two hurdles are met, a reviewing court then considers whether the agency's interpretation is an official position, implicates substantive expertise, and reflects "fair and considered judgement" independent of litigation.
- If the reviewing court deems that each of these factors is satisfied and that the agency's interpretation is warranted by Congress, then, and only then, is *Auer* deference to be granted.

Kisor v. Wilkie, Secretary of Veterans Affairs

- The Court Elaborated On 3 points
  - An official agency interpretation must emanate from agency officials through official vehicles which make authoritative policy.
    - Thus, for example in the Medicare appeals context the action of the MAC does not constitute the official position of the agency.
  - The court should not defer to the agency's own interpretations that have been developed as litigating positions.
    - Not a *post hoc* rationalization advanced in litigation to defend the agency's action and was not developed and proffered in any previous official regulatory actions by the agency.

Kisor v. Wilkie, *Secretary of Veterans Affairs*

- When deference is granted under *Auer*, deference is not greater than *Chevron* deference
  - *Auer* deference, as *Chevron* deference, applies to only to a reading by the agency which is "within the bounds of reasonable interpretation"
- Time will tell how the courts apply *Kisor*, but the explanation and limitation on Auer deference inures to the benefit of the party challenging a regulation.

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