Limits on Agency Action by the Department of Health and Human Services: Impact on Providers in 2020 and Beyond

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Agenda

- Case law review
  - *Azar v. Allina Health*
  - *Kisor v. Wilkie*
  - *Department of Commerce*
  - *Universal Health Services v. US ex rel. Escobar*
- Policy Implementation
- Implications for government's COVID response
- Hypotheticals

Azar v. Allina Health Services

- The court considered whether in 2014 (for FY 2012 cost reports) CMS's inclusion of Part C days in the DSH Medicare fraction was acceptable in the absence of notice and comment rulemaking
  - CMS had previously lost a case in which the court invalidated its 2004 rulemaking on the same issue because of insufficient notice

Azar v. Allina Health Services (cont.)

- The court noted that the Medicare Act itself requires CMS to provide notice and a chance to comment on any "rule, requirement, or other statement of policy" that "establishes or changes a substantive legal standard governing . . . the payment for services." 42 U.S.C. §1395hh(a)(2).
- The question is one of what is a "substantive legal standard?"
- The hospitals suggested that it is anything that imposes duties, rights, or obligations on a party, as opposed to *procedural* standards, which discuss means of enforcement of those standards
- The government argued that the difference is between "interpretive" and "substantive" standards, with the latter having the force and effect of law, and the former being guidance on how the agency is interpreting the law.

Azar v. Allina Health Services (cont.)

- The Court ruled in favor of the hospitals for several reasons:
  - The Government's interpretation would render the statute internally inconsistent
  - The Medicare Act doesn't cross-reference the interpretive rule exemption from the APA
  - The Government's arguments regarding the legislative history were not persuasive to the Court
  - The Government's claim to the burdens of having to go through notice and comment rulemaking were overstated
    - Most of the Manual provisions, for instance, likely would be considered "procedural"

Azar v. Allina Health Services (cont.)

- The dissent, however, made a number of important observations:
  - The Majority's opinion stops short of definitively accepting the "substantive" versus "procedural" distinction, but merely declined to accept the "substantive" versus "interpretive" distinction
  - The Majority's opinion does not clarify whether *any* impact on payment automatically turns a rule into a substantive rule
    - For instance, what about instances where the statute requires action, but the agency doesn't go through notice and comment rulemaking
  - The Majority's opinion reopens for consideration all of the cases where a court held the agency's action acceptable on the basis that it was based on an "interpretive rule"

Kisor v. Wilkie, Secretary –Department of Veteran's Affairs

- Not a Medicare case, but important for administrative law generally
  - Basic legal question: **How should a Court review an agency's interpretation of its own regulations?**
- Legal doctrine known as "*Auer* deference"
  - Judicial deference given to an agency's interpretation of its own regulation unless it did not comport with the plain language of the regulation, or was otherwise "plainly erroneous."
  - Legal observers looked to this case to determine whether the court would modify this standard of review.

Kisor v. Wilkie, Secretary –Department of Veteran's Affairs

- The Court did not overturn *Auer* deference
  - "Auer deference retains an important role in construing agency regulations."
- But…
  - "Even as we uphold it, we reinforce its limits."
  - "*Auer* deference is sometimes appropriate and sometimes not."

Kisor v. Wilkie, Secretary –Department of Veteran's Affairs

- The Court set forth limitations of the *Auer* doctrine and the considerations for determining when such deference applies.
  - "Potent in its place but cabined in its scope."
- The Court began by providing a historical explanation of its legal basis for extending deference to agency regulatory interpretations
  - Grounded in a presumption of Congressional intent – Congress would want the agency to play the primary role in resolving regulatory ambiguities.
  - Agencies are more grounded than courts in the policy concerns affecting the regulated parties.
  - Benefits of uniformity of interpretation.

Kisor v. Wilkie, Secretary –Department of Veteran's Affairs

- But deference only arises when a regulation is "genuinely ambiguous"
  - Court – "we mean it."
  - After all standard tools of interpretation have been exhausted.
- Moreover, "not all *reasonable* agency constructions of those truly ambiguous rules are entitled to deference" except to the extent they have the "power to persuade"
  - If genuine ambiguity exists the agency's reading must still be reasonable – that is, it must come within the zone of ambiguity identified by the court.
  - Interpretation must be the agency's "authoritative" or "official position."
  - It must "implicate the agency's substantive experience."
  - It must reflect "fair and considered judgment."

Kisor v. Wilkie, Secretary –Department of Veteran's Affairs

- So where does the decision leave us? The Court described it well:

  "The upshot of all of this goes something as follows. When it applies, *Auer* deference gives an agency significant leeway to say what its own rules mean. In doing so, the doctrine enables the agency to fill out the regulatory scheme Congress has placed under its supervision. But that phrase 'when it applies' is important—because it often doesn't…this Court has cabined *Auer's* scope in varied and critical ways---and in exactly that measure, has *maintained a strong judicial role in interpreting rules*. What emerges is a deference doctrine not quite so tame as some might hope, but not nearly so menacing as they might fear."

Department of Commerce v. New York

- Issue: When may a court go beyond the administrative record and inquire into the mental processes of administrative decisionmakers?
- The plaintiffs challenged as pretextual the Secretary of Commerce's decision to reinstate a citizenship question on the census form. District court found pretext and permitted extra-record discovery because:
  - DOJ requested reinstatement of question for Voting Rights Act (VRA) enforcement after Commerce tried to elicit requests from other agencies.
- The Supreme Court found a mismatch between the Secretary's action and rationale (DOJ VRA enforcement).
  - District court's remand to the agency was therefore appropriate.

Department of Commerce v. New York

- First Principles:
  - "[I]n order to permit meaningful judicial review, an agency must disclose the basis of its action."
  - "[A] court is ordinarily limited to evaluating the agency's contemporaneous explanation in light of the existing administrative record. … [F]urther judicial inquiry into 'executive motivation' represents a 'substantial intrusion' … and should normally be avoided."
  - "[A] court may not reject an agency's stated reasons for acting simply because the agency might also have had other unstated reasons," or "set aside an agency's policymaking decision solely because it might have been influenced by political considerations … ."

Department of Commerce v. New York

- Exception:
  - A court may inquire into the mental processes of administrative decisionmakers and obtain extra-record discovery upon a "strong showing of bad faith or improper behavior."
- The Court "agree[d] with the Government that the District Court should not have ordered extra-record discovery when it did"
- But materials later added to the administrative record showed that VRA played an insignificant role, late in the decisionmaking process, making it appropriate for the Court to review the District Court's pretext ruling "in light of all the evidence in the record"

U.S. ex rel. Escobar v. Universal Health

- Relators were the parents of 17-year-old daughter.
- Parents brought daughter to a counseling center for treatment.
- Most of the staff members who treated daughter were not licensed mental health professionals.
- Daughter died from an adverse reaction to anti-psychotic medications.

U.S. ex rel. Escobar v. Universal Health

- The relator's allegations:
  - The staff members who treated their daughter were unlicensed and unsupervised.
  - The facility's claims used codes corresponding to services that the staff members were not qualified to provide.
  - The facility violated more than a dozen state Medicaid regulations.

U.S. ex rel. Escobar v. Universal Health

- U.S. Supreme Court affirmed that implied certification "*can be a basis for liability*" "*at least in certain circumstances*."

  What matters is not the label the Government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision.
- Vacated and remanded to the First Circuit
  - Were the violations in question material to the government's payment decision?

U.S. ex rel. Escobar v. Universal Health

- U.S. Supreme Court determined that "materiality" "…cannot rest '*on a single fact or occurrence as always determinative*.'"
  - Condition of payment is itself a "*relevant*" though "*not dispositive*" factor in determining materiality.
  - Materiality must be assessed based on the government's actual and expected conduct.

U.S. ex rel. Escobar v. Universal Health

- “The FCA is not an all purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations.”
- “A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a CoP.”

U.S. ex rel. Escobar v. Universal Health

- "…proof of materiality can include, but is not necessarily limited to evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on compliance with the particular statutory, regulatory, or contractual requirement."
- "Materiality cannot be found where noncompliance is minor or insubstantial."

U.S. ex rel. Escobar v. Universal Health

- Examples of "very strong evidence" that requirements <u>are not material</u>:

  "…if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material."

  "…if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position."

“It is the policy of the United States to alleviate unnecessary regulatory burdens placed on the American people.”

~ Executive Order 13777 of February 24, 2017

Policy Implementation

Curtailing Regulation by Guidance

DOJ Sessions Memo

- "Guidance may not be used as a substitute for rulemaking and may not be used to impose new requirements on entities outside the Executive Branch."
- "Nor should guidance create binding standards by which the Department will determine compliance with existing regulatory and statutory requirements."

DOJ Brand Memo

- "The Department may not use its enforcement effort authority to effectively convert agency guidance documents into binding rules."
- "Some guidance documents simply explain or paraphrase legal mandates … and the Department may use evidence that a party read such a guidance document to help prove that the party had the requisite knowledge."

HHS Clearance Process

- HHS OGC clears proposed rules, guidance documents, statements of policy.

Traits of Guidance Documents

- Disclaim force or effect of law
- Do not coerce persons into taking action or refraining from taking action
- No new mandatory language
- Clear statement that compliance is voluntary

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DOJ Granston Memo

Grounds for Voluntarily Dismissing Actions Under the False Claims Act

01	**The Merits**	"[A] qui tam complaint is facially lacking in merit—either because relator's legal theory is inherently defective, or the relator's factual allegations are frivolous."
02	**Opportunism**	A qui tam action "duplicates a pre-existing government investigation and adds no useful information to the investigation."
03	**Interference with the Agency**	"[A]n agency has determined that a qui tam action threatens to interfere with an agency's policies or the administration of its programs and has recommended dismissal to avoid these effects."
04	**Control of Litigation**	"[DOJ] should consider dismissing cases when necessary to protect [DOJ's] litigation prerogatives."
05	**Safeguarding Information**	"In certain cases, particularly those involving intelligence agencies or military procurement contracts, we should seek dismissal to safeguard classified information."

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DOJ Granston Memo

Grounds for Voluntarily Dismissing Actions Under the False Claims Act

06	**Preserving Resources**	"[DOJ] should also consider dismissal under section 3730(c)(2)(A) when the government's expected costs are likely to exceed any expected gain."
07	**Procedural Errors**	"[DOJ] may also seek dismissal of a qui tam action pursuant to section 3730(c)(2)(A) based on problems with the relator's action that frustrate the government's efforts to conduct a proper investigation."
	Notes	• DOJ's position is that the appropriate standard for dismissal under section 3730(c)(2)(A) is the "unfettered" discretion standard adopted by the D.C. Circuit rather than the "rational basis" test adopted by the 9th and 10th Circuit. The latter standard, however, is deferential. • The factors for dismissal are not mutually-exclusive, and DOJ may rely on multiple grounds for dismissal. There may also be additional grounds for dismissal. • DOJ is not obligated to proceed in an all or nothing matter; it may seek only partial dismissal of some defendants or claims. • ***DOJ "should consult closely with the affected agency as to whether dismissal is warranted under any of the factors set forth" in the Granston Memo.***

Cleary/Jenny Memo

Allina and CMS Enforcement Actions

Impact of Allina Problem

- If CMS "issued guidance that, under Allina, should have been promulgated through notice-and-comment rulemaking, the … ability to bring enforcement actions predicated on violations of those payment policies is restricted. If [CMS] intends for a particular guidance document to be used in enforcement actions, then the guidance must comply with Allina."

Limits of Guidance

- "[T]o the extent that IOMs and similar guidance set forth payment rules that are not closely tied to statutory or regulatory standards, the government generally cannot use violations of that guidance in enforcement actions, because under Allina, it was not validly issued."

OGC View on FCA Actions

- "In the context of healthcare qui tam suits, components of HHS are the government payors, so the critical question is whether the alleged violation would have influenced our decision to pay. Guidance documents, in conjunction with the government's payment history, may shed light on this question.".

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CMS COVID Rulemaking

- Interim Final Rule (display copy published March 13, 2020)
  - Addresses telehealth, inpatient “under arrangements” billing, IRF visits, and other matters

- Interim Final Rule (display copy published April 28, 2020)
  - Addresses telehealth, outpatient department billing, GME and teaching physician billing

- Inpatient Notice of Program Rulemaking (published in the Federal Register on May 29, 2020)
  - Includes codification of many of CMS’s bad debt policies only included in Manual provision previously

New Policy Initiatives

What will be the impact post-COVID-19?

EO 13991: Improved Agency Guidance Documents

- Amplifies Brand and Sessions memos
- Calls for public input into guidance documents
- Orders creation of guidance databases
- Establishes procedures for issuing guidance

EO 13992: Civil Administrative Enforcement and Adjudication

- Amplifies Brand and Sessions memos
- No unfair surprise when judging conduct
- Bases for jurisdiction must be published
- Opportunity to contest determination required

Legal Authorities

- SBREFA § 213
- *Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632 (6th Cir. 2004)
- OLC Opinion 77-80

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Hypotheticals

- Hypo 1:
  - CMS has a largely unwritten policy that states that a hospital that has previously not been a teaching hospital and has no FTE cap nevertheless sets its per-resident amount (PRA) as soon as residents train onsite pursuant to a “planned” rotation

Hypotheticals (*cont*.)

- Hypo 2:
  - Hospital determines that it hasn't been issuing "notices of coinsurance liability" at an off-campus provider-based clinic, notwithstanding a regulatory requirement to do so. The Provider-Based Rule expressly states that provider-based status only applies when *all* of the requirements in the regulation are met

Hypotheticals (*cont*.)

- Hypo 3:
  - A MAC states on its website that, before a physician office lab can bill for a test, the ordering physician must be “linked” to the physician practice through an 855R. Health System discovers that it has not done so. Does it have a duty to disclose and/or repay?

Hypotheticals (*cont*.)

- Hypo 4:
  - A MAC rejects a provider's attestation of provider-based status based on a letter from an official in the CMS Regional Office in Chicago due to certain areas of the provider-based department sharing space with another provider.

Hypotheticals (*cont*.)

- Hypo 5:
  - The PRRB dismisses an appeal due to an untimely filing of a preliminary position paper. There is no statute or regulation governing the timing.

Hypotheticals (*cont*.)

- Hypo 6:
  - The IRF regs require a post-admission screening by a rehab physician within 24 hours of the patient's admission. This is labeled a "condition of payment." Hospital determines that physicians have waited until the following Monday to perform the admission when admitted on the weekend. The visits are otherwise medically necessary and required services have been furnished. Duty to repay? Duty to disclose?