Morgan Lewis

FAST BREAK: 2019 OPPS RULE

Andy Ruskin and Jake Harper

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Agenda

- CMS's final changes from the 2019 OPPS Rulemaking
- Litigation challenges to CMS's OPPS policies
- Implications for determining the ideal operational structure for clinics

Provider-Based Status

- OPPS Rule impacts both "excepted" and "nonexcepted" provider-based clinics
- Becoming provider-based is not without its challenges
- Requires
  - Licensure
  - Clinical integration
  - Financial integration
  - Public awareness
  - Administrative integration
  - Medicare beneficiary billing requirements
  - COP/JC requirements

Provider-Based Status *(cont.)*

- Other drawbacks include:
  - Patient dissatisfaction with dual coinsurance
  - Physician dissatisfaction with loss of autonomy

Provider-Based Status *(cont.)*

- As of 1/1/17, enhanced payment is not always available, even if provider-based status applies
- The Bipartisan Budget Act of 2015 created a new taxonomy
  - Entities paid under OPPS
    - On-campus provider-based clinics
    - Provider-based clinics within 250 yards of a remote location
    - DEDs (on-campus or off-campus)
    - Provider-based clinics that billed under OPPS prior to 11/2/15
  - Other off-campus provider-based clinics are referred to as "nonexcepted" and are paid 40% of the OPPS rate

CY 2019 OPPS Rule

- Published in the 11/21/18 Federal Register
- Went into effect on 1/1/19
- Included provisions pertaining to provider-based clinics, as follows:
  - Off-campus DED modifier
  - E/M site neutrality
  - Reimbursement for 340B Drugs in nonexcepted provider-based clinics
  - Expansion of services at nonexcepted provider-based clinics

CY 2019 OPPS Rule *(cont.)*

- CMS has a concern (echoing MedPAC) with significant growth in number of off-campus DED's
- CMS therefore intends to monitor the extent to which services are shifting from other sites to DEDs
- Created a modifier "ER"
- References the need for the ED to be integrated with the hospital, and that the hospital must be large enough to address the ED's needs for inpatient beds

CY 2019 OPPS Rule *(cont.)*

- E/M Site Neutrality
  - CMS has expressed a concern with the growing volume of E/M services furnished in the HOPD, relative to physician office E/M services
  - CMS cites a number of sources as evidence of E/M volume issues, including:
    - Increases in OPPS spending overall
    - A GAO report indicating that physician practice acquisitions from 2007 to 2013 resulted in a shift of E/M services from physician offices to HOPDs
  - As a result, CMS is phasing in over two years a policy that reduces E/M to the nonexcepted off-campus provider-based rate for excepted off-campus provider-based clinics
    - This will *not* be budget neutral and will presumably save $610 million for Medicare
  - CMS 's supposed legal support for the policy is a statutory provision that allows CMS to come up with a "method" for control unnecessary volume increases

CY 2019 OPPS Rule *(cont.)*

- Reimbursement for 340B Drugs
  - CMS has stated that it believes that the differential for 340B drugs between excepted and nonexcepted off-campus, provider-based clinics has created undue incentives to shift utilization of 340B drugs to nonexcepted sites
  - CMS has therefore reduced payment to these sites to ASP-22.5%, just as with excepted sites
  - CMS bases this policy on its ability to decide what the "applicable payment system" is under the Bipartisan Budget Act

CY 2019 OPPS Rule *(cont.)*

- CMS proposed to limit the expansion of services that could be furnished in nonexcepted provider-based clinics
- Revivification of a proposal from 2016
- Decided, again, that would be too burdensome to implement
- Should still consider, when changing service lines, whether the site will qualify as the same "department" (i.e., same medical director, line on the cost report, etc.)

CY 2019 OPPS Rule *(cont.)*

- If comparing off-campus outpatient clinics now with physician offices, physician offices compare quite favorably
- E/M services are paid about the same
- But . . .
  - For 340B covered entities, *physician offices potentially receive higher payment for infused drugs*
- And physician offices do not have issues with dual coinsurance or loss of physician autonomy

CY 2019 OPPS Rule *(cont.)*

- One reason to continue to remain provider-based or continue to open new provider-based clinics would be 340B contract pharmacy prescriptions
- HRSA's current policy is that contract pharmacy prescriptions must be written at child sites
- Child sites must be identified as reimbursable cost centers on the cost report
- Though generally thought of as provider-based clinics billing on a 1450, there's nothing that dictates such a limitation

Recent Litigation

- *AHA v. Azar* (18-2084, DDC, decided 12/26/18)
  - Considered CMS's CY 2018 rule regarding reduction of payment for 340B drugs in excepted off-campus outpatient departments
  - Determined that hospitals did not need to appeal on a claim-by-claim basis
    - Relied on case law for the proposition that the claims appeal process could be waived after consideration of "whether judicial resolution of the issue will interfere with the agency's efficient functioning, deny the agency the ability to self-correct, or deprive the Court of the benefits of the agency's expertise and an adequate factual record."
    - Given the unequivocal nature of the agency's rulemaking and the rules regarding what is binding on ALJs, the court decided that waiver was appropriate

Recent Litigation *(cont.)*

- *AHA v. Azar* (18-2084, DDC, decided 12/26/18) *(cont.)*
  - CMS also claimed that the court was precluded from judicial review of the agency's action because there was no express right to judicial review under the statute
  - Court held that it could review if the agency acted *ultra vires*, which it concluded that it had
  - CMS claimed that the 340B payment reduction was a mere "adjustment" as permitted by statute
  - Court determined that the reduction was a "fundamental change" and not an "adjustment." Therefore, the court struck down the policy.
  - Relief is an injunction, but due to budget neutrality considerations, the court has requested more briefing
  - CMS can still appeal

Recent Litigation *(cont.)*

- Challenges to site-neutrality
  - In December, 2018, AHA filed a suit against CMS challenging its site neutrality policy, claiming that CMS's reliance on the statutory provision allowing for volume control safeguards is misplaced
    - There is a significant probability that the Court will again find that the claims appeal process can be waived for all the same reasons
    - There is also a likelihood that the argument regarding "ultra vires" action will again trump any concerns about judicial review preclusion

Recent Litigation *(cont.)*

- Challenges to site-neutrality
  - This week, it was announced that several private parties entered into a group action against CMS reinforcing AHA's efforts
  - Appealing separate from AHA has several advantages
    - The plaintiffs could be part of any settlement discussions
    - The plaintiffs could advocate for expeditious payment of lump sum monetary relief, rather than waiting for the agency to redo its rule and then pay in accordance with its new rule
    - The plaintiffs, as directly aggrieved parties, could seek separate payment, even if the outcome of the AHA litigation results only in prospective changes to the OPPS system

Implications of Litigation for Organizational Structure of Clinics

- For excepted, off-campus clinics:
  - Providers that have remained provider-based after the 2018 rule presumably have already determined that the cuts for 340B drugs did not justify converting to freestanding services
  - Factors in favor of keeping provider-based status include:
    - 340B contract pharmacy utilization
    - Potential for recouped E/M payments upon conclusion of the litigation
  - Factors in favor of converting to freestanding include:
    - Physician and patient satisfaction
    - Fewer compliance issues
  - Can probably switch back and forth between the two statuses, but will not get retrospective payments

Implications of Litigation for Organizational Structure of Clinics *(cont.)*

- For nonexcepted, off-campus clinics:
  - Factors in favor of keeping provider-based status include:
    - 340B contract pharmacy utilization
    - Potential for recouped reimbursement for 340B drug utilization
    - Potential for recouped E/M payments upon conclusion of the litigation
  - Factors in favor of converting to freestanding include:
    - Physician and patient satisfaction
    - Fewer compliance issues
    - Higher reimbursement, should the 340B drug utilization cases not prevail
  - Can also consider seeking to become a reimbursable cost center that is *not* a provider-based HOPD

QUESTIONS?

Thanks!

Andy Ruskin
Partner
Washington, DC
+1.202.739.5960
andrew.ruskin@morganlewis.com
Click Here for full bio

Andy counsels hospitals, pharmaceutical and medical device companies, and Medicare Advantage plans, among others, on a range of Medicare and Medicaid regulatory, litigation, and transactional matters. Andy advises on strategic issues surrounding coverage, reimbursement, and compliance, as well as drug pricing and price reporting. He defends clients in investigations by the US Attorney's Office and the Department of Health and Human Services Office of Inspector General, and he appears before several regulatory tribunals, such as the Provider Reimbursement Review Board and the HCPCS Committee.

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Fast Break: GDPR

Featuring Axel Spies

- February 21, 2019 3:00 PM (EST)