



Boston Bar Association Medicare CLE Fall 2014

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- ACA Implementation Begins
- The Doc Fix
- Major Proposal to Revise Part D Stalls
- HRSA Loses a 340B Court Decision
- CMS Payment Rules – Status Quo

ACA Implementation

- The biggest surprise with ACA implementation is that after all of the problems late last year/early 2014, the Administration met its ACA enrollment goals.
- The biggest challenge was how unprepared states that operated their own exchanges were.
 - Massachusetts no exception

- Massachusetts Experience
 - Significant problems with state-run Exchange
 - Serious consideration given to joining federal Exchange in 2015 but that does not now seem likely
 - Enrollment of individuals into temporary Medicaid has posed serious challenges for Medicaid managed care plans in Massachusetts.

- Two looming challenges for ACA in 2015:
 - How will the open enrollment season go this Fall? What will 2015 premiums look like?
 - What is the ultimate disposition of *Halbig v. Burwell* in the DC Circuit or potentially the Supreme Court?

The “Doc Fix”

- Perennial issue because of flaw in SGR formula that Congress doesn’t want to pay for.
 - This necessitates annual Medicare physician fee schedule bills that act as a train to pull along other health care policy riders.
- Early optimism that this was the year that Congress could permanently resolve the issue faded.

The “Doc Fix”

- Of note in this year’s bill: a significant change to the system by which Medicare pays for diagnostic lab services.
- Lab payment in Medicare has really not been updated since the mid-1980s, with some minor tweaks in 2001.
- The system currently in place does not reflect the complexity of new molecular diagnostic tests, so Congress substantially revised the payment system.

The “Doc Fix”

- The new payment system moves to a market-based payment model and away from government-imposed price setting.
- When fully phased in (January, 2017), Medicare payment will be based on the weighted median for private payers for the test.
- Labs must begin reporting on private payment rates in 2016
 - Similar to ASP reporting for Part B drugs.
- New Advanced Diagnostic Laboratory Tests will be paid at actual list charges for three quarters before the transition to the market system.

Medicare Part D

- CMS made a serious attempt to make the most significant changes to Medicare Part D since the program began in 2006 earlier this year.
- CMS proposed:
 - To re-interpret the “non-interference” clause;
 - To remove “protected class” status for anti-depressants, anti-psychotics, and immunosuppressants used for organ rejection; and
 - To drastically limit the ability of Part D plans to develop preferred pharmacy networks.

Medicare Part D

- CMS faced enormous pressure from some (but not all) stakeholders to withdraw its rule.
- On the day that comments closed in March, CMS announced that it would not move forward with the most controversial changes.
- Highly unlikely that CMS will advance these proposals again in this Administration.

- This is not really a CMS issue at all but does affect CMS stakeholders.
- This is the year that manufacturers began to push back against HRSA's perceived "kowtowing" to covered entities.
- The agency lost a court case that doesn't affect a large number of drugs but has serious implications for the program long-term.

- ACA expanded list of covered entities to include pediatric hospitals; cancer hospitals; CAHs; sole community hospitals; and rural referral centers.
- But, Congress exempted orphan drugs from 340B pricing for those covered entities.
- A HRSA rule defined “orphan drug” to mean a drug only when dispensed for its orphan indication.
- PhRMA sued on APA grounds, challenging the HRSA interpretation.

- HRSA lost the case at the District Court level and is currently trying to decide whether to appeal to the DC Circuit.
- The central reason for the court's decision was that the statute does not grant authority for HRSA to issue binding regulations to implement the program.
- This calls into question the legal effect of much of the guidance that HRSA has issued since the program began in the early 1990s as well as a “mega-rule” that HRSA had planned to issue this summer.

CMS Payment Rules

- By and large, the IPPS, PFS and HOPPS payment rules (IPPS Final; PFS and HOPPS proposed) were fairly status quo rules.
- In an unexpected pleasant surprise to MA hospitals, the wage index “rural floor” was continued in this year’s IPPS rule due to the 2010 census designation of Greenfield and the consequent status of Franklin Medical Center as a “Lugar Hospital.”
- CMS’ view now seems to be: if Congress does not like this policy, Congress must overturn it.

Conclusion

- Could have been a major year for CMS policy changes but never materialized.
- Depending on the outcomes of the 2014 elections, it is possible that there will be a large Medicare/Medicaid bill next year.
- In the short-term, a “doc fix” bill has to pass by the spring of 2015 but a larger bill is possible – maybe even on a bipartisan basis.