Policy Brief

September 6, 2019

Price Transparency – What's the Discussion?

Although price transparency has been a longstanding issue in policy discourse, the Trump Administration has made this a top priority. In 2018, CMS finalized a rule requiring hospitals to post their Chargemaster online. This year, President Trump signed an Executive Order requiring hospitals to post their negotiated rates with insurers. The Outpatient Prospective Payment System (OPPS) proposed rule implements the Order and specifically requires hospitals to post the negotiated rates of 300 shoppable procedures. According to CMS Administrator Seema Verma, this is just the beginning of more to come. However, questions remain on whether publishing hospitals' charges and negotiated rates will truly be meaningful to consumers and lower the cost of care. **Click here to explore the arguments currently being debated.**

The Opioid Crisis: Lessons from *Oklahoma v. Purdue Pharma, et al.*

"As a matter of law I find that Defendants' [Johnson & Johnson] actions caused harm and those harms are the kinds recognized by [the Oklahoma nuisance statute] because those actions annoyed, injured, or endangered the comfort, repose, health or safety of Oklahomans."

On August 26th, Judge Thad Balkman of Cleveland County, OK, issued this verdict in the landmark case of *Oklahoma v. Purdue Pharma, et al*. The ruling is one of the first handed down in a flurry of litigation seeking restitution for pharmaceutical companies' role in the opioid epidemic. Between 2012 and 2017, opioids claimed nearly 200,000 lives in the U.S.

What precedent does this set?

Oklahoma v. Purdue—if the verdict remains intact after J&J's promised appeal—will likely remain a legal anomaly in the opioid battle. The breadth of Oklahoma's public nuisance statute makes it easier than in other states to bring a claim based on malicious practices that capitalized on addictive and deadly opioids. It's unlikely we will see many nuisance-based opioid claims elsewhere.

While the $527 million judgment against J&J is significantly less than the $17 billion the state asked for, Judge Balkman directed the funds to be applied to the State Abatement Plan (SAP), ensuring the money will support infrastructure for fighting the opioid epidemic. Combined with settlements from Purdue Pharma and Teva, the J&J verdict brings Oklahoma's total recovery to about $1 billion—enough to cover two years of the SAP.

This approach contrasts from Big Tobacco settlements, which were critiqued for massive cash infusions that were poorly managed by states and often did little to address population health. However, the SAP matched with the $527 million figure, could give other litigants a sense of what is reasonable in negotiations and effective for fighting the opioid epidemic in their states.

What about other states?

U.S. Civil Procedure allows for similar cases to be consolidated under Multi-District Litigation (MDL). The National Prescription Opiate Litigation is consolidated under MDL 2804, and involves allegations against manufacturers, distributors, physicians and pharmacies for a growing class of plaintiffs. The current MDL alone is estimated to represent $480 billion in damages, raising speculation that a national opioid settlement would be unparalleled in terms of the final figure.

Already, the biggest opioid manufacturers have started making offers to enter into something that would mirror the National Settlement Agreement with Big Tobacco in the 1990s. Just a day after the verdict against J&J was announced, Purdue proposed a national settlement of $10-12 billion. With Purdue's future uncertain, states may be compelled to take what they can get before the pharma giant declares bankruptcy.

Immigration Changes Jeopardize Pediatric Health

The U.S. Citizenship and Immigration Services (USCIS) recently sent letters to immigrant families announcing that it will no longer consider deferred deportation for children undergoing serious medical treatment, giving families 33 days to leave the country. The letters are especially concerning to hospitals treating immigrant children with rare and serious diseases. USCIS' actions join other policy changes, such as the public charge and Supplemental Nutrition Assistance Program rules, that make it harder for parents, pediatricians and other providers to keep kids healthy.

What are medical deferred actions?

Medical deferred actions allow immigrant children with acute care needs to receive treatment in U.S. hospitals. Families requesting "deferred action" can stay in the country for up to two years to get life-saving treatment. Children battling cancer, cerebral palsy, cystic fibrosis and other serious conditions use the program to purchase care they are unable to receive in their country of origin.

What has changed?

USCIS began mailing letters dated August 7th to parents applying for renewal, stating that it would no longer accept or process medical deferment requests. Over 100 members of Congress denounced the change, calling the decision one that "will needlessly endanger vulnerable children and families." Advocates urge the Administration to instead explore changes through rulemaking, so that health researchers, physicians and child advocates can provide guidance.

What's next?

Because the change was not made through the traditional rulemaking process, it is difficult to predict exactly what USCIS will do next. In a newly-released statement, the Trump Administration stated it will process cases that were already in progress but made no commitment to preserving the program. Clarity is still needed on whether the medical deferred action program will be ended once pending cases are resolved.

340B Litigation Update

On Tuesday, September 3rd, Secretary Alex Azar submitted his Appellant's Brief to the U.S. Court of Appeals for the District of Columbia in an ongoing battle over the 28.5% cut to 340B reimbursement rates. Here are some of his key positions:

- The District Court lacked jurisdiction to hear the claim because rules like OPPS are precluded from judicial review by the Medicare statute.
- OPPS must operate in a budget neutral manner, making remedial measures possibly more disruptive.
- Higher Medicare payment rates for 340B drugs result in higher costs to beneficiaries.

Read the full brief here. AHA's Appellees' Brief is due September 24th.

A Look at the Federal Register

Confidentiality for Substance Use Disorder Patient Records

The Substance Abuse and Mental Health Services Administration released a proposed rule (84 FR 44568) related to confidentiality under 42 CFR Part 2 as it applies to Substance Use Disorder (SUD) in patient medical records. The rule clarifies and expands a non-opioid treatment provider's ability to discuss and redisclose SUD, provided that the patient discloses the information to that provider. Comments close October 25th.

CDC Revised Recommendations for HIV Testing of Adults, Adolescents and Pregnant Women

The CDC has issued a notice with comment period (84 CFR 45495) as it seeks updates to its 2006 HIV testing guidelines, including best practices for screening and connected care. Comments close October 28th.

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U.S. Judge Orders Big Drug Companies to Face Opioid Trial – Reuters

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