Policy Brief

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(Adam Zyglis, The Buffalo News.)

Pharma Pays for Fueling Opioid Crisis

Last Monday, California, Hawaii, Maine and the District of Columbia sued Purdue Pharma, bringing the total number of states filing lawsuits against the company to 48. The states seek to hold the company and its owners, the Sackler family, accountable for downplaying the risks of addiction when marketing OxyContin to doctors. Years of lawsuits and investigations have pointed to the family intentionally exploiting those with Substance Use Disorder (SUDs) for profit. For example, many revealing documents came to light during a 2007 lawsuit where Purdue plead guilty and paid $634 million for criminal drug misbranding charges. Below is more about the Sackler family's role in the opioid epidemic and how the government is cracking down on opioid manufacturers.

Numerous court documents found that the Sackler family was confronted with evidence of their drug's addictiveness as soon as six months after it gained FDA approval in 1996. Instead of trying to curb the growing misuse, the Sackler family is accused of exploiting it by using aggressive marketing strategies to target those with SUDs. Richard Sackler, the previous CEO and current board member of Purdue, wrote in an email, "We have to hammer on the abusers in every way possible. They are the culprits and the problem. They are the reckless criminals." Kathe Sackler, also a company board member, instructed

employees to pursue Project Tango, a plan to raise revenue by targeting those with SUDs to sell them Suboxone, an opioid addiction treatment.

The federal and state governments continue to crack down on manufacturers and distributors alleged of contributing to the opioid crisis. In May, the first of over 1,600 civil lawsuits against Purdue Pharma was settled for $270 million. Several other drug companies are also being sued; Insys Therapuetics paid $225 million to settle claims alleging it illegally marketed a highly addictive fentanyl painkiller to doctors. This April, the Department of Justice brought criminal charges to an opioid distributer for the first time for failing to report thousands of suspicious opioid orders. Within the next few years, we expect to see a growing number of cases and settlements, such as the Johnson & Johnson trial, attempting to hold pharma companies accountable for the numerous deaths.

Tax-Exempt Hospitals Face Growing Scrutiny

Legislators across the nation are questioning whether not-for-profit hospitals are providing enough community benefit to justify their tax-exemption. On February 19th, U.S. Senator Grassley wrote a letter to the Internal Revenue Service (IRS) inquiring about hospitals' compliance with the community benefit requirements set by the Affordable Care Act (ACA). Legislators in California, Florida, Colorado and Oregon have also increased their scrutiny, introducing bills that would allegedly make not-for-profit hospitals more accountable. These efforts will likely continue, placing pressure on hospitals to expand community investments and improve community benefit reporting.

Colorado

HB 1320, enacted into law May 16th, requires all not-for-profit hospitals to complete annual Community Health Needs Assessments (CHNAs) and Community Health Implementation Strategies. The bill also requires hospitals to report the list of investments that were included in Part I, II and III on the Schedule H (part of the IRS form 990). For any identified health need, hospitals most describe available evidence showing that the investment improves community health outcomes.

Oregon

HB 3076 requires the state to set a minimum for hospitals' community benefit spending. It also requires not-for-profit hospitals to report specific information to the state each year, such as property tax exemption status, charity care provided, income margins and reserves. Hospitals that fail to file a timely report may be subject to a civil penalty not to exceed $500 per day.

Florida

HB 1295, which failed to pass, proposed that hospitals document the value of charitable services provided to the community. Under this proposal, hospitals would have only received a property tax exemption proportional to the value of charitable services provided, as reported on Schedule H of the 990 form. Additionally, community benefit statements would have been required to be signed by the hospital’s CEO and a certified public accountant.

California

AB 204, which passed the House and is awaiting a vote in the Senate, proposes that the value of hospitals’ charity care be calculated using a percentage of Medicare allowable rates as determined by the Office of Statewide Health Planning and Development (OSHPD). Additionally, the bill requires hospitals that are part of hospital systems to report on community benefits as separate entities instead of as a system as allowed under current law.

The Great Divide on Drug Pricing

Lowering drug prescription prices is an issue that has received overwhelming bipartisan support. After months of hearings and requests for information, the House of Representatives has finally passed a legislative package of bills aimed to lower prescription drug prices. The bill has provisions supported by

Republicans and Democrats alike. Yet, most say its legislative future is in dire straits. Why does a bill that embodies such a bipartisan effort have a grim legislative fate? READ MORE to find out.

The House just passed one of the largest health care bills of the year and its aim is to lower drug prices. The bill allows a second generic version of a prescription to be approved before the first generic is available on the market. Research shows that once there is more than one generic prescription available, the cost of the prescription drops significantly. The bill also bans pay for delay agreements. This is a practice where the manufacturer of a brand-name prescription pays the company that develops the generic to not bring their drug to the market. This allows the brand-name company to control the market. Another major provision allows generic manufacturers to sue in court for samples and ingredients of prescriptions when brand-name manufacturers stall in sharing that information.

Despite these bipartisan solutions, the bill's fate is still grave. Progressive Democrats have tepid support because they want provisions within the bill that would allow the government to set and negotiate drug prices regardless of payer. The Republican controlled Senate isn't likely to take up the bill because it includes several provisions that bolster the ACA. These provisions include rolling back short-term plans and reneging on the Trump Administration's push to allow states to make changes to their Health Insurance Exchanges through waiver requests. Although this bill is unlikely to become law, Democrats can tout its passage in the 2020 election. Tackling drug prices will continue to be a bipartisan priority and more legislative activity is likely to take place.

HHS Proposes Rolling Back Antidiscrimination Protections

The Department of Health and Human Services' (HHS) Office of Civil Rights has proposed a rule revising antidiscrimination provisions of the ACA. The ACA's definition of health care discrimination included gender identity—protecting transgender patients from unfair treatment or compromised access to care. The proposed revision removes this protection. It also removes provider requirements to supply translation and other language-access resources for patients, to post antidiscrimination notices at care locations and on websites, and to have a set grievance procedure for discrimination complaints. HHS believes that by rolling back these protections, it will save roughly $3.6 billion, as organizations would no longer have to process grievances or address lawsuits brought by transgender patients. For a more detailed summary, click here.

VA Launches New Private Care Program

As of June 6th, The Department of Veterans Affairs (VA) launched a new initiative for veterans seeking care outside of VA hospitals. The new Veterans Community Care Program aims to expand options for veterans experiencing difficulty in getting care. Veterans can be seen by private providers if they have to drive more than 30 minutes to their primary care doctor, need services not provided at the VA or have to wait more than 20 days for an appointment. Some veterans' health advocates are concerned that the program's launch is premature. Between juggling a new HIT software, bill payment errors and a history of past-due payments, critics wonder whether the VA is truly ready to keep up with an increased influx of private-sector claims. No regulation governing prompt payment was included in the final rule, however, the VA expects to undertake "rulemaking to implement prompt pay provisions" in the future.

A Look at the Federal Register

Reducing Administrative Burden to put Patients over Paperwork. CMS is seeking comments via a Request for Information on ideas to progress their Patients over Paperwork initiative and provide deeper perspective on ways to relieve burden in: 1) Reporting and documentation requirements; 2) Coding and documentation requirements for Medicare or Medicaid payment; 3) Prior-authorization procedures; 4) Policies and requirements for rural providers, clinicians and beneficiaries; 5) Policies and requirements for dually enrolled (i.e., Medicare and Medicaid) beneficiaries 6) Beneficiary enrollment and eligibility determination; 7) CMS' processes for issuing regulations and policies. *This comment opportunity hasn't been fully published on the Federal Register.* **Comments are due August 12, 2019.**

Protecting Statutory Conscience Rights in Health Care; Delegations of Authority. The Office for Civil Rights (OCR) finalized a rule that revises existing regulations to ensure enforcement of federal conscience and anti-discrimination laws for recipients of HHS funds. In addition, this final rule clarifies OCR's authority to initiate compliance reviews, conduct investigations, supervise and coordinate compliance by HHS and use enforcement tools otherwise available in existing regulations to address violations and resolve complaints. **The rule is effective July 22, 2019.**

Veterans Community Care Program. The VA finalized a rule amending its regulations that govern VA health care. The final rule allows veterans to receive necessary hospital care, medical services, and extended care services from non-VA entities or providers in the community. **The rule is effective June 6, 2019.**

Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE). CMS released a final rule that updates the requirements for PACE under the Medicare and Medicaid programs. The rule addresses application and waiver procedures, sanctions, enforcement actions and termination, administrative requirements, PACE services, participant rights, quality assessment and performance improvement, participant enrollment and disenrollment, payment, federal and state monitoring, data collection, record maintenance, and reporting. The changes will provide greater operational flexibility, remove redundancies and outdated information, and codify existing practice. **The rule is effective August 2, 2019.**

State-Level Paid Family Leave Policy Project. HHS is seeking comment on a proposed information collection activity that will explore the relationship between women's health and state-level paid family leave (PFL) programs, which provide partial wage replacement to eligible employees to bond with a new child. The project aims to increase awareness of women's health effects in relation to state-level PFL programs among key stakeholders, including advocates, state and federal policymakers, and state program administrators. This information will be used to inform the national conversation about these programs. **Comments are due July 10, 2019.**

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