

(R-ME) and Claire McCaskill (D-MO) — have sent letters asking naloxone manufacturers to explain their price increases. Though these requests recall recent investigations into Mylan, the manufacturer of the EpiPen, the naloxone situation has not garnered the type of attention or outrage inspired by that case, perhaps in part because of the stigma associated with opioid use.

There are additional steps governments could take to address naloxone's price increase. First, naloxone could be purchased in bulk, which would create stable demand that might motivate additional companies to begin manufacturing the medication — a strategy that's been used for vaccine manufacturing. Second, governments could invoke federal law 28 U.S.C. section 1498 to contract with a manufacturer to act on behalf of the United States and produce less costly versions of Evzio's patented auto-injector in exchange for reasonable royalties — an approach that was considered for procuring ciprofloxacin during the anthrax threat in 2001.⁴ Third, in response to increases in generic drug prices,

some observers have proposed allowing importation of generics from international manufacturers that have received approval from regulators with standards comparable to those of the FDA,⁵ a strategy that could be pursued for naloxone.

In the long term, the FDA could also offer incentives to additional companies to obtain approval to market generic versions of naloxone by prioritizing more timely approval and waiving application user fees, which may require congressional action but would probably stimulate price competition. In the past, the FDA has discussed switching naloxone to over-the-counter status,² a conversation that could be revisited given the expected benefits for patient access. The relative ease of receiving FDA authorization for over-the-counter medications would also probably attract additional manufacturers.

Naloxone coprescribing and expanded availability represents only one of many potential strategies for reducing the number of prescription-opioid and heroin overdose deaths in the United States. But when governments promote

naloxone use, they have a responsibility to ensure the drug's affordability. Taking action now is essential to ensuring that this lifesaving drug is available to patients and communities.

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All-Payer Claims Databases — Uses and Expanded Prospects after *Gobeille*

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Health care spending is approaching 20% of the U.S. gross domestic product, yet spending on research to improve the functioning of the health care system has been limited. What is worse, we generally lack a unified source of data to study all persons and the services they receive. Medicare data are national

in scope but are limited primarily to people over age 65 and are not representative of behaviors or spending for the commercially insured.¹ Furthermore, since Medicare's prices are set administratively, its data cannot be used to study issues such as market power and competition. Data from commercial health insurers are lim-

ited because each plan represents only a portion of the market and enrollees frequently change plans.

To address these gaps, 16 states have established all-payer claims databases (APCDs), which gather health insurance eligibility, provider, and claims data, including payment information, from virtually all payers in a state to create

a complete picture of health care provided. Despite this momentum and the usefulness of APCDs, the Supreme Court's March 2016 decision in *Gobeille v. Liberty Mutual* struck a major blow to the viability of APCDs by prohibiting state-mandated reporting from self-insured employer plans,² which cover more than half of commercially insured Americans. Yet, paradoxically, *Gobeille* may improve the prospects for APCDs.

Maryland created the first APCD in 1995, and coast to coast 15 states, both Republican and Democratic, have followed suit, with more in the process of doing so (see timeline). A key feature of APCDs is the inclusion of prices paid for services, which are otherwise publicly unavailable because such information is considered proprietary. Data on prices are useful to support price-transparency efforts, which are increasingly important to consumers, particularly given the widespread adoption of high-deductible health plans that shift the financial burden of health care decisions onto them. New Hampshire was the first to publish price information, through its NHHealthCost.org website.³

Data from APCDs also can be used directly to inform state policy and for market regulation. Several years after passing its health care reform program, Massachusetts found that increases in health care costs were threatening the long-term viability of its insurance expansions. In 2012, state legislators set a goal of keeping the growth of health care costs at or below the rate of growth in the gross state product. The state has relied on APCD data⁴ to monitor increases in spending by provider systems and insurers, and these data were also crucial to a state court's 2015 decision to bar

Partners HealthCare from acquiring South Shore Hospital, which the state argued would result in higher prices and spending.

APCDs also permit marketwide measurement of quality, using measures such as those in the Healthcare Effectiveness Data and Information Set (HEDIS). Combining data across payers enhances the statistical power of measurement, allowing assessment of practices that may be too small to have a sufficient number of patients from a single insurer and inclusion of enrollees in smaller health plans that might otherwise be omitted from analyses. Similarly, accountable care organizations (ACOs) can use pooled all-payer data to assess their population health efforts, benchmarked against those of regional or national leaders. APCDs also allow public health officials and policymakers to monitor the incidence and prevalence of acute and chronic diseases and to study issues such as practice-pattern variation and disparities in care. Finally, APCDs provide opportunities for researchers and others to better understand the health care system and to test interventions to improve care.

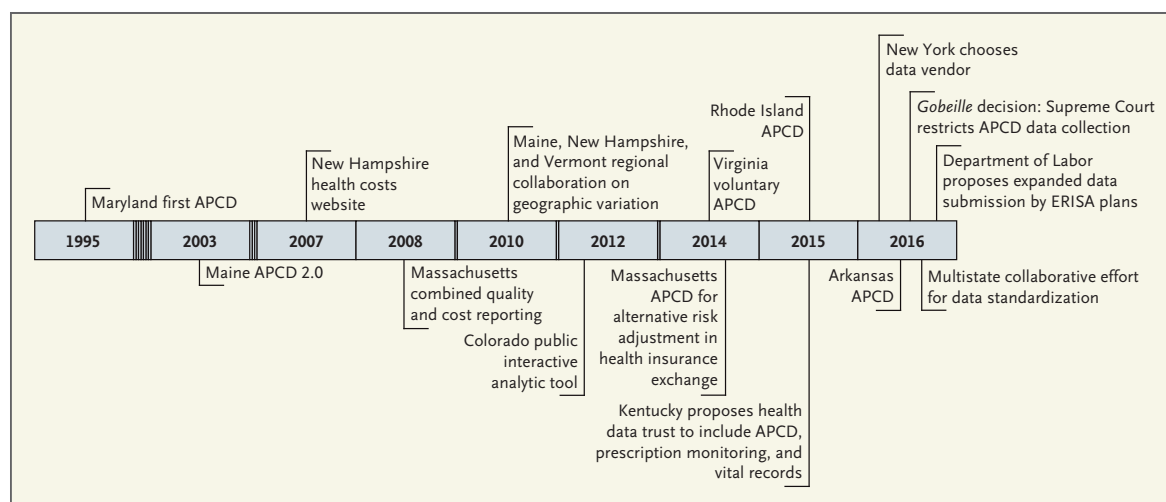
Yet APCDs face hurdles beyond the *Gobeille* ruling that the Employee Retirement Income Security Act preempts state laws requiring insurers to report claims data to a state agency. First, APCDs are resource-intensive. Massachusetts spent \$7.6 million running its APCD in 2015 — a substantial amount, though only about 0.01% of total state health spending. Consequently, funding and sustainability are important considerations. Some states look to recoup costs through data licensing fees, though many observers believe that APCD data (with appropriate protections) should be eas-

ily available at minimal cost to a diverse user community.

Second, payers often object to APCD reporting requirements layered on top of existing data requirements, such as mandates to file product and rate information with insurance regulators and quality reports with public health authorities, among others. States can develop partnerships with insurers that recognize the burden on payers and seek to reduce redundancy. Although APCDs appear to be yet another burden placed on industry, they could ultimately reduce the burden for insurers; an APCD permits cross-agency use of a single data source to meet multiple requirements. In Massachusetts, shared APCD data have replaced many plan filings with insurance regulators and the health insurance exchange.

Third, data quality is a challenge. Because each insurer has its own data system and structure, as well as unique product- and provider-identification systems, submitted data may not fully conform to the state's specifications. Some data fields are simply unavailable in insurers' systems. Accurately linking provider and patient identities across time and across carriers is also difficult, yet it's essential to unlocking the full power of the APCD. Progress continues on master patient indexes to follow patients across time and master provider indexes that map providers to medical groups and networks, but much work remains.

Finally, particularly in the post-*Gobeille* era, a key determinant of the success of APCDs will be the ability of states to obtain complete and timely data. Although *Gobeille* is a major setback for state action on APCDs, the decision also suggested a federal path forward. The Court's majority



Timeline of Selected APCD Developments throughout the United States.

ERISA denotes Employee Retirement Income Security Act.

suggested that states could obtain self-insured plan data through the Department of Labor (DOL), which has regulatory authority over self-insured plans and could require that the data be shared with state APCDs. The DOL proposed last July to expand plan reporting and require submission of data, possibly including the data that would otherwise be lost owing to *Gobeille*.⁵ Thanks to coordinated efforts by multiple organizations and APCD states, a common data layout for all states will soon be available to guide the DOL's final rule. The result will be a single national standard for claims-data submission, greatly simplifying the process for payers and states alike. Furthermore, once the self-insured standards are in place, they will most likely become the de facto standard for fully insured plans, too, further simplifying and streamlining the data-submission process for insurers and the aggregating and analysis efforts of APCDs. Indeed, the new standards should dramatically reduce the time and resources needed for a state to establish and operate

an APCD and for health plans to submit their data.

Achieving the Triple Aim — better experience of care, better population health, and lower costs — will require comprehensive understanding of health care markets and practice, and current data sources remain inadequate. Despite challenges, APCDs offer multiple benefits for health system improvement, health policy, and research. Although the health policy priorities of the new administration are not yet articulated, bipartisan desire for more efficient operation of Medicare and Medicaid as well as greater transparency of price and quality suggest that the need for accurate timely data — that is, APCDs — will not change. New federal rules prompted by the *Gobeille* decision could lead to more widespread availability of APCDs in the next decade. In a dramatic turnaround from the pessimism of March, new DOL rules and a common data standard may clear the path to broader, and more cost-effective, establishment and expansion of APCDs in other states.

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