



CENTER FOR HEALTH LAW & POLICY INNOVATION Harvard Law School

Submitted via the Federal eRulemaking Portal

U.S. Department of Labor
Office of Regulations and Interpretations
Employee Benefits Security Administration
Attn: RIN 1210-AB63
Annual Reporting and Disclosure, Room N-5655
200 Constitutional Avenue NW
Washington, DC 20210

December 5, 2016

Re: EBSA-2016-0010; RIN 1210-AB63: Comments on the Proposed Rules Amending the Annual Reporting and Disclosure Requirements of the Employee Retirement Income Security Act

To Whom It May Concern:

We are writing on behalf of the Center for Health Law and Policy Innovation. We appreciate the opportunity to provide comments to the Department of Labor (DOL) on its recently proposed rules amending the annual reporting and disclosure requirements required under Part I of Subtitle B of Title I of the Employee Retirement Income Security Act of 1974 (ERISA) to satisfy Public Health Service Act (PHS Act) Sections 2517A and 2717. In particular, we value that DOL is mindful of the impact of the Supreme Court's recent decision in *Gobeille v. Liberty Mutual Insurance Co.*, 136 S. Ct. 936 (2016), and is attempting to take steps to continue collecting data previously available to the public in states' All-Payer Claims Databases (APCDs). We thank you for your commitment to ensuring important sources of data relied on by health care researchers and policymakers are not lost in light of *Gobeille*.

While we applaud the proposed rule's attempts to expand the information collected from group health plans and insurance issuers, we are concerned that the proposal will not adequately replace the content and comprehensiveness of the data lost from state APCDs. Similarly, we are concerned that merely requiring reports annually will negatively impact the abilities of researchers and policymakers to swiftly implement necessary changes in our health care system that save lives and scarce resources. Last, we worry that the lack of uniformity between the federal data collection format and the format used in existing state APCDs will create administrative barriers for states and researchers attempting to combine these resources into one database.

To continue providing health care researchers and policymakers with a comprehensive database of health care claims information that is vital for lifesaving research and unavailable from other sources, we urge DOL to consider the recommendations and comments detailed below.

Recommendation One: Expand the Types of Information that Must Be Disclosed by Group-Health Plans and Health Insurance Issuers

We strongly support DOL's proposal to require group-health plans and health insurance issuers to submit information on health plan enrollment and claims.¹ While the proposed regulations are a step in the right direction, we urge DOL to expand the information collected in order to better serve health service researchers and policymakers working to identify reforms that effectively drive down health care costs, evaluate the relative utility of different treatment options, and detect instances of discrimination in the provision of care.² Such necessary and important goals cannot be achieved using the limited types of information DOL currently plans to collect and the type of information contained in state APCDs cannot be obtained from other sources.

We urge DOL to align the proposed reporting requirements with the APCD Council's³ recommended best practices, which provide useful guidance for the types of information a model APCD should collect. Statewide APCDs typically include data derived from medical claims, pharmacy claims, eligibility files, provider (physician and facility) files, and dental claims from private and public payers.⁴ Such claims data includes patient demographics (DOB, gender, ZIP code); diagnosis, procedure, and National Drug Codes; information on service provider; prescribing physician; health plan payments; member payment responsibility; type and date of bill paid; facility type; revenue codes; and service dates.⁵ Although DOL's proposal requires group health plans and insurance issuers to submit claims processing and payment information (i.e. the number of claims filed, paid, appealed, and denied) and service provider information,⁶ this information is very much on the macro level⁷ and will not capture the detailed, patient-

¹ Annual Reporting and Disclosure, 81 Fed. Reg. 47,499-47,500 (proposed July 21, 2016) (to be codified at 29 C.F.R. pts. 2520 and 2590). The proposed regulations require non-grandfathered group health plans and health insurance issuers to provide (1) claims payment policies and practices, (2) periodic financial disclosures, (3) data on enrollment and disenrollment, (4) data on the number of denied claims, (5) data on rating practices, (6) information on cost-sharing and payments with respect to any out-of-network coverage, (7) information on enrollee and participation rights, and (8) other information as determined by the Secretary.

² See *Gobeille*, 136 S. Ct. at 950-51 (Ginsburg, J., dissenting).

³ The APCD Council is a learning collaborative of government, private, non-profit, and academic organizations focused on improving the development and deployment of state-based APCDs. See APCD Council, *About APCD Council*, <http://www.apcdouncil.org/about-apcd-council> (last visited Sept. 16, 2016).

⁴ Lucy Hodder, et al., *Model All-Payer Claims Database Legislation*, 2, APCD Council and West Health Policy Center, (May 2015) <http://www.apcdouncil.org/publication/model-all-payer-claims-database-legislation>.

⁵ Jo Porter, et al., *The Basics of All-Payer Claims Databases: A Primer for States*, 2, APCD Council, (Jan. 2014) <http://www.apcdouncil.org/basics-all-payer-claims-databases-primer-states>.

⁶ Annual Reporting and Disclosure, 81 Fed. Reg. 47,500 (proposed July 21, 2016) (to be codified at 29 C.F.R. pts. 2520 and 2590).

⁷ Group health plans will be required to submit the new Schedule J and report data including the total number of people covered by the plan at the end of the year, the total number of post-service benefit claims appealed during the year, and the total dollar amount of health benefit claims paid during the year. See Proposed Revision of Annual Information Return/Reports, 81 Fed. Reg. 47,635-36 (proposed July 21, 2016) (to be codified at 29 C.F.R. pts. 2520 and 2590).

specific information that was previously collected by state APCDs and relied on by researchers and policymakers.

The necessity of requiring expanded claims information is evident when one considers the unique types of research APCDs support. Academic medical centers and universities use APCDs as tools for understanding cost, utilization, and quality of health care as well as for generating recommendations regarding health care policy.^{8,9} This research is vital to improving the American health care system by identifying cost trends relating to price transparency, hospital provider and patient out-of-pocket costs, and location and performance of intra-state health care markets.¹⁰ For instance, research based on APCD data has been used to identify discrepancies in the way doctors prescribe psychotropic prescriptions to children enrolled in Medicaid compared to children who are commercially insured, and variation in the rates of prescription between regional health service areas.¹¹ Such research relies on detailed information that the proposed regulations fail to collect, including medical claims information and patient demographics, in order to reveal significant disparities in the quality of health care received by Medicaid insured children. Absent changes to the regulations that broaden the data collected, researchers and policymakers will be losing a key resource for identifying unwarranted practice variation and for improving the effectiveness of health care and the efficiency of use of scarce and expensive resources.¹²

Recommendation Two: Increase the Frequency with which Group-Health Plans and Health Insurance Issuers Must Report

We urge DOL to increase the frequency with which group health plans and health insurance issuers must submit information. Unlike the proposed regulation requirements, APCDs often require health insurance providers to submit information monthly or quarterly, depending on the number of individuals served.¹³ As DOL recognized in its proposal, data collected annually

⁸ Brief for Harvard Law School Center for Health Law and Policy Innovation et al. as *Amici Curiae* 11-12, *Gobeille v. Liberty Mutual Insurance Co.*, 136 S. Ct. 936 (2016), http://www.scotusblog.com/wp-content/uploads/2015/09/Amicus_brief_Gobeille_v_Liberty_Mutual_09_2015.pdf.

⁹ APCD data is also important for addressing clinical care issues, such as health status, disease management, pregnancy management, medication safety, hospital quality, and hospital-associated infections. *Id.*
¹⁰ *Id.* at 12.

¹¹ Shelsey J. Weinstein, *Small Geographic Area Variations in Prescription Drug Use*, 132 PEDIATRICS 3 (Sept. 2014). The study found that prescription use among Medicaid-enrolled children was 62% higher than use among commercially insured children.

¹² Brief for Harvard Law School Center for Health Law and Policy Innovation et al. as *Amici Curiae* 25.

¹³ See *Gobeille*, 135 S. Ct. at 941; see also Code of Vt. Rules 21-040-021, §§ 4, 6(I) (2016) (CVR) (requiring health plans with greater than 2,000 members to report monthly and plans with between 500 to 1,999 members to report quarterly); The Commonwealth of Massachusetts for Health Information and Analysis, *The Massachusetts All-Payer Claims Database Medical Claim File Submission Guide* 5 (Feb. 2016), <http://www.chiamass.gov/assets/docs/p/apcd/submission-guides/version-5.0/v5-apcd-medical-claim-file-submission-guide-FINAL.pdf> (requiring medical claims information to be submitted monthly); Maryland Health Care Commission, *2016 Medical Care Data Base: Data Submission Manual* 5 (Nov. 17, 2015) http://mhcc.maryland.gov/mhcc/pages/apcd/apcd_mcdm/documents/2016_MCDB_Submission_Manual_20160128.pdf (requiring submission of data quarterly); MedInsight NH CHIS, *New Hampshire Comprehensive Health Care Information System* 8 (Mar. 10, 2016),

under the proposed regulations “will not be timely for use in concurrent oversight, enforcement, or consumer choice activities.”¹⁴ By extension, the data gathered under the new reporting requirements will hinder the abilities of researchers and policy makers to identify and react to problematic health care services trends or dangerous medications in a timely manner.

The frequency with which information is submitted is essential for being able to use the data collected to actively monitor and improve health services. For instance, Maine’s APCD data was used to develop a drug claims model to predict prescription opioid abuse.¹⁵ This type of model can be used to screen patients receiving opioid prescriptions or notify providers if patients meet certain key risk factors,¹⁶ something several states have expressed interest in utilizing as a clinical tool to help combat the ongoing opioid abuse epidemic.¹⁷ However, if data was only collected annually, it would delay both the development and application of such helpful models and slow states’ responses to critical health care issues affecting their populations.

In addition to being used to actively monitor and improve health services, APCDs have also been used to identify treatment effect heterogeneity – or how individuals respond to a particular treatment, intervention or stimulation. These rare but dangerous reactions to treatments can be impossible to identify without large, diverse data sets, like those contained in a APCDs, and the frequency with which data is submitted is a crucial factor affecting researchers’ abilities to quickly identify adverse reactions that could cost unknowing patients their lives. For instance, research by a Swedish team was able to use APCD data to determine that a monoclonal antibody used to treat Crohn’s disease and multiple sclerosis was correlated with development of a progressive multifocal leukoencephalopathy (PML), a serious and usually fatal viral infection resulting in inflammation of the brain.¹⁸ This study was particularly important because the drug examined was successful at reducing the progression of disability in patients affected by multiple sclerosis by forty-two to fifty-four percent.¹⁹ By analyzing detailed APCD data, the researchers were able to identify this rare but fatal reaction and the factors making a patient more likely to develop PML,²⁰ resulting in improved overall safety for patients. Due to APCDs’ role in identifying dangerous and fatal treatment effects, we urge DOL to increase the frequency with which reporting entities submit information so that researchers are able to identify treatment effect heterogeneity more quickly and prevent the loss of countless lives.

<https://nhchis.com/Documents/DataSubmission/2016%20NH%20Data%20Submission%20Manual.pdf> (requiring carriers and third-party administrators that have 10,000 or more New Hampshire members and carriers that offer products on the health insurance exchange to report monthly).

¹⁴ Annual Reporting and Disclosure, 81 Fed. Reg. 47,500 (proposed July 21, 2016) (to be codified at 29 C.F.R. pts. 2520 and 2590).

¹⁵ Alan G. White et al., *Analytic Models to Identify Patients at Risk for Prescription Opioid Abuse*, 15 AM. J. MANAGED CARE 12 (Dec. 2009).

¹⁶ *Id.* at 901.

¹⁷ *See id.*

¹⁸ Gary Bloomgren et al., *Risk of Natalizumab-Associated Progressive Multifocal Leukoencephalopathy*, 366 NEW ENG. J. MEDICINE 1870-80 (May 2012).

¹⁹ *Id.* at 1871.

²⁰ *Id.*

Recommendation Three: Clarify DOL's Intentions and Extend the New Reporting Requirements to All Group-Health Plans and Health Insurance Issuers

Gobeille significantly limited the availability of comprehensive APCDs that can be utilized by researchers and policymakers. An estimated 61% of Americans receiving health insurance through their employers are covered by self-insured plans that are now not required to submit health care claims data to APCDs.²¹ Critically, data from a single type of payer does not represent the entire population, and therefore, is not as helpful for improving the effectiveness and efficiency of the health care system. For instance, individuals insured by Medicaid tend to represent a poorer, sicker segment of the population while those insured by Medicare are older.²² APCDs are one of the only data sources with health care claims from the entire population in a state, and thus, are critically important for developing recommendations about the best clinical care that can be generalized to the entire population.²³

The importance of having a comprehensive database to conduct health service research was observed in a 2012 study using only Medicaid data from Tennessee. The study reported that patients using azithromycin, an antibiotic commonly prescribed and historically thought to be safe to use for treating respiratory infections and some sexually transmitted infections, had a two to three times higher risk of death from cardiovascular causes than individuals taking amoxicillin or not using antibiotics.²⁴ The findings from this study, which were intended to help physicians and patients weigh the risks and benefits of using azithromycin over other similar medications, could have seriously impacted the standard course of care for common infections. In response, Danish researchers used their country's comprehensive national registries²⁵ to find there was no risk of increased cardiovascular death associated with azithromycin use, citing the comprehensive dataset, analogous to an APCD, as helpful for obtaining results that were widely generalizable.²⁶ The Danish researchers distinguished their results from the Tennessee study by noting that the risks associated with this common antibiotic may be limited to high-risk populations, like the Medicaid population which has poorer health, but that their results based on a large, nationally representative population were likely widely generalizable to young and middle-aged adult populations.²⁷ Had doctors relied solely on the results from the study analyzing Medicaid data, the standard course of care for treating common infections could have been unnecessarily undermined.

²¹ *Gobeille*, 136 S. Ct. at 952 (Ginsburg, J., dissenting) (citing Brief for Harvard Law School Center for Health Law and Policy Innovation et al. as *Amici Curiae* 20).

²² Brief for Harvard Law School Center for Health Law and Policy Innovation et al. as *Amici Curiae* 16, 18-19, 22.

²³ *Id.*

²⁴ Wayne A. Ray et al., *Azithromycin and the Risk of Cardiovascular Death*, NEW ENG. J. MEDICINE 366 (May 17, 2012).

²⁵ Danish registries are not strictly APCDs since Denmark's government is the only payer, however, the registries collect all health care claims for the Danish population.

²⁶ See Henrik Svanstrom et al., *Use of Azithromycin and Death from Cardiovascular Causes*, NEW ENG. J. MEDICINE 368 (May 2, 2013).

²⁷ *Id.*

Given the necessity of a comprehensive database in order to conduct meaningful and lifesaving research, we urge DOL to clarify which group health plans are covered by the new reporting requirements. While the transparency provisions of the Affordable Care Act that are incorporated in section 2715A of the PHS Act only apply to non-grandfathered group health plans and insurance issuers offering non-grandfathered group or individual health insurance coverage,²⁸ other proposed DOL regulations indicate that all group health plans subject to ERISA will be required to file the new Schedule J.²⁹ Since twenty-three percent of covered workers were enrolled in grandfathered health plans in 2016,³⁰ a large amount of data previously captured by APCDs will be lost if grandfathered plans are exempt from the new reporting requirements. If it was not DOL's intention to require all group health plans subject to ERISA to submit data, we urge DOL to use its authority under ERISA to mandate that all ERISA plans with more than 100 participants comply with the new reporting requirements in order to best maintain a comprehensive source of data that researchers and policymakers rely on for life-saving research and important policy decisions.

Recommendation Four: Ensure that the Data Reporting Format Adopted by DOL is Compatible with the Format of Existing State APCDs

We recommend that DOL convene a task force with the states, health insurance industry, and other interested parties to ensure the data collection format DOL plans to use is compatible with the existing format of state APCDs. While DOL says it took “into account differences in markets and other relevant factors to streamline reporting under multiple reporting provisions,”³¹ it is not clear from the proposed regulations whether DOL also considered the administrative burden on researchers and states that want to combine existing state APCDs with the data DOL collects. As discussed before, prior to *Gobeille* state APCDs were among the few databases that provided large and diverse enough data sets to power certain statistical analyses that are necessary to understand the health system and identify treatment-effect heterogeneity.³² In order for researchers to reassemble the comprehensive data necessary to conduct research essential to the health care industry, they will need to combine state and federally collected data. Depending on the formats used by each, this could become a very burdensome process for a researcher to undertake. Adopting a common data format after consulting with all interested parties could eliminate this obstacle for states and researchers and help ensure that their expertise and time is spent conducting life and resource saving analyses.

²⁸ Annual Reporting and Disclosure, 81 Fed. Reg. 47,499-47,500 (proposed July 21, 2016) (to be codified at 29 C.F.R. pts. 2520 and 2590). A non-grandfathered group health plan is a plan that was purchased before the Affordable Care Act went into effect in 2010; *see* U.S. Centers for Medicare & Medicaid Services, *Grandfathered Health Plan*, <https://www.healthcare.gov/glossary/grandfathered-health-plan/> (last visited Sept. 23, 2016).

²⁹ Proposed Revision of Annual Information Return/Reports, 81 Fed. Reg. 47,556-57 (proposed July 21, 2016) (to be codified at 29 C.F.R. pts 2520 and 2590).

³⁰ The Kaiser Family Foundation and Health Research & Educational Trust, *2016 Employer Health Benefits Survey, Summary of Findings* (Sept. 14, 2016), <http://kff.org/report-section/ehbs-2016-summary-of-findings/>.

³¹ Annual Reporting and Disclosure, 81 Fed. Reg. 47,500 (proposed July 21, 2016) (to be codified at 29 C.F.R. pts. 2520 and 2590).

³² Brief for Harvard Law School Center for Health Law and Policy Innovation et al. as *Amici Curiae* 24-25, 27.

In order to ensure consistency and continuity of the new data standard, DOL should provide minimum thresholds for the completeness and accuracy of the data elements. For example, the numeric code to indicate the service provided to a patient may need to be 100% completed and 95% accurate. DOL could institute these thresholds explicitly in the rule or incorporate it by reference to a work product of a working group that has more thoroughly studied the issue.

Similarly, to ensure that the reporting format adopted by DOL continues to be the optimum data collection format as treatments and the health care industry continue to evolve, DOL should detail a process in the regulations for periodically updating the data format. This could be done by delegating the responsibility to an advisory committee consisting of representative stakeholders, including state APCDs, state policymakers, consumers, insurers or third-party administrators, experts in health claims data, and health service researchers.

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We believe these suggestions will help ensure that the analytic power of APCDs is not lost in light of *Gobeille* while also making APCDs more useful and more efficient by eliminating many of the administrative obstacles for states, ERISA plans, and others interested in utilizing this valuable data. Together, these effects will aid researchers, policymakers, and advocates who are working to ensure that all Americans have access to better, more affordable health care.

Please contact Carmel Shachar with the Center for Health Law and Policy Innovation at cshachar@law.harvard.edu if we can be of any assistance.

Thank you for your consideration of these comments.

Respectfully submitted by:

The Center for Health Law and Policy Innovation