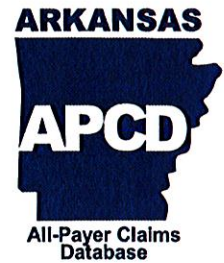


Comments on Department of Labor Notice of Proposed Rulemaking
Docket # EBSA-2016-0010; RIN 1210-AB63
Submitted by the Arkansas Center for Health Improvement on behalf of the
Arkansas Healthcare Transparency Initiative Board



On July 21, 2016, the Department of Labor (DOL) and coordinating agencies published a Notice of Proposed Rulemaking^[1] and a Notice of Proposed Revision of Annual Information Return/Reports^[2] proposing changes to the Form 5500 annual report for employee benefit plans. We are responding to DOL's request for public comments on "those conforming amendments and the proposed annual reporting requirements for plans that provide group health benefits, including the new Schedule J, in light of the Supreme Court's recent decision in *Gobeille v. Liberty Mutual Insurance Co.*, 136 S. Ct. 936 (2016)."^[3]

The National Academy for State Health Policy (NASHP) and the All-Payer Claims Database (APCD) Council (a collaboration between the National Association of Health Data Organizations (NAHDO) and the Institute for Health Policy at the University of New Hampshire) have submitted detailed comments proposing an approach to support DOL's need for data and information by leveraging existing infrastructure and investment in state APCDs to collect claims data.

On behalf of the Arkansas Healthcare Transparency Initiative Board, the Arkansas Center for Health Improvement expresses support for the approach described in the NASHP/APCD Council comments. A collaboration between DOL and states to implement a pilot program and adopt a standardized set of healthcare claims data is beneficial and addresses the needs identified by DOL for oversight of the quality and cost of health care provided by Employee Retirement Income Security Act plans, which are among the stated objectives of DOL's creation of Schedule J.

We respectfully request that DOL review the approach brought forward in the NASHP/APCD Council comments and consider state partnership in the development of final rules for Form 5500 and Schedule J.

Sincerely,

A handwritten signature in blue ink, appearing to read "Joe Thompson". The signature is fluid and cursive.

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^[1] 81 Fed. Reg. 47496 (July 21, 2016).

^[2] 81 Fed. Reg. 47534 (July 21, 2016).

^[3] 81 Fed. Reg. 47534, 47559 (July 21, 2016).



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Submitted by the National Academy for State Health Policy (NASHP), in collaboration with National Association of Health Data Organizations (NAHDO), and the APCD Council

On July 21, 2016, the Department of Labor (DOL) and coordinating agencies published a Notice of Proposed Rulemaking¹ and a Notice of Proposed Revision of Annual Information Return/Reports² proposing changes to the Form 5500 annual report for employee benefit plans. We are responding to DOL’s request for public comments on “those conforming amendments and the proposed annual reporting requirements for plans that provide group health benefits, including the new Schedule J, in light of the Supreme Court’s recent decision in *Gobeille v. Liberty Mutual Insurance Co.*, 136 S. Ct. 936 (2016).”³

These comments are submitted by the National Academy for State Health Policy (NASHP), in collaboration with The National Association of Health Data Organizations (NAHDO), and the APCD Council, reflecting the views of States that have enacted laws establishing all-payer claims database reporting laws. All-payer claims databases (APCDs) are large-scale, State-run databases that collect health care claims data and provider data from all types of payers in the State, including private insurers, public payers, dental insurers, prescription drug plans, State employee health plans, and others. APCDs gather data for each patient encounter that can be used to better understand health care payments, quality, and utilization. Eighteen states have or are in the process of establishing APCDs, which are critical tools for regulators and researchers to oversee health care costs and quality,⁴ and are recognized in the Affordable Care Act (ACA) as an important vehicle for making cost information about local health care providers available to consumers and employers.⁵

On March 1, 2016, the Supreme Court dealt a substantial blow to state APCDs in *Gobeille v. Liberty Mutual Ins. Co.*, holding that the Employee Retirement Income Security Act (ERISA) preempts Vermont’s APCD reporting law with respect to health benefit plans offered on a self-funded basis by private employers. As a result of the decision, many data reporters have curtailed or ceased submitting health care claims data to State APCDs, depriving States, researchers, and the public of essential information on health care costs, quality, and utilization.

We understand that the Form 5500 and Schedule J are designed to address specific, important annual reporting purposes for DOL. Nevertheless, Schedule J could be augmented to better serve DOL’s oversight of and improve transparency of group health plans. We support DOL’s implementation of Schedule J, but propose DOL study the collection of additional health care claim and related data from ERISA plans under Schedule J through pilot programs in States with APCD capacities.

We make the following comments on the proposed amendments to Form 5500, particularly Schedule J, in light of the *Gobeille* decision, as explained in more detail below. We propose a way for DOL to address the loss of health care claims and related data engendered by the *Gobeille* decision, and supply model rule text the DOL could promulgate to effectuate our proposal.

1. The proposed rule regarding changes to the Form 5500 and Schedule J is insufficient to meet the goals under ERISA and the ACA of greater transparency and oversight of health care cost and quality – goals

¹ 81 Fed. Reg. 47496 (July 21, 2016).

² 81 Fed. Reg. 47534 (July 21, 2016).

³ 81 Fed. Reg. 47534, 47559 (July 21, 2016).

⁴ APCD COUNCIL, www.apcdouncil.org.

⁵ ACA Section 1003, enacting Public Health Service Act section 2794(d)(1)(D).

served by State data collection but imperiled by the *Gobeille v. Liberty Mutual* decision. Specifically, adopting a rule that allows submission of Schedule J, as proposed, to fully satisfy the reporting obligations for health plans, would foreclose the opportunity to gather additional data to help DOL meet its stated goals of improving plan transparency and conducting oversight over group health plan compliance, and preserve the transparency gains created by States' work with APCDs.

2. DOL has the statutory authority to require self-funded plans to submit health care claims and related data under Public Health Service Act (PHSA) §§ 2715A and 2717, which were incorporated into ERISA and applied to group health plans by ERISA § 715, as well as under ERISA §§ 104 and 505.
3. We propose that DOL, pursuant to its authority under PHSA §§ 2715A and 2717 and ERISA §§ 104 and 505, require as part of Schedule J that group health plans submit a standardized health care claims and related dataset (the "Common Data Layout"), to be tested through a pilot program in collaboration with States with APCD data collection capacity. The adoption of the Common Data Layout will minimize cost and burden on ERISA plans and adhere to ERISA's statutory goals of uniformity, consistent with the Supreme Court's decision in *Gobeille*. To further reduce the burden on ERISA plans, all ERISA plan data, self-funded and fully-insured, could be submitted using the Common Data Layout.
4. Recognizing the technical and operational complexity of DOL building a system to collect health care claims data, we suggest that DOL pursue a pilot approach to test how partnering with State APCDs through cooperative agreements under ERISA § 506 can assist DOL with its oversight and analysis through Schedule J. The APCDs could annually report aggregated data drawn from the Common Data Layout to DOL as part of Schedule J reporting and analysis. Such a collaboration between DOL and State APCDs will minimize unnecessary duplication and expense and preserve the value of the substantial investment in state APCDs that was made through federal grants to states to develop these databases under PHSA § 2794. The pilot programs could begin immediately, while the effective date of the rest of Schedule J could be delayed until plan year 2019 as proposed.

1. The Proposed Rule is insufficient to restore the loss of data caused by the *Gobeille v. Liberty Mutual* decision and insufficient to meet the goals of the ACA.

The proposed data elements and amendments to Form 5500 and Schedule J may be effective for DOL's annual reporting purposes, but are insufficient to fully address the ACA's aim to expand oversight to the quality and cost of health care provided by ERISA plans, which are among the stated objectives of DOL's creation of Schedule J.

- A. Additional and more frequent data reporting than would be required by the proposed Schedule J are needed to meet DOL's stated goals of oversight of group health plans' quality and cost.

Schedule J could be augmented with the type of data collected by APCDs to better serve DOL's oversight of and improve transparency of group health plans.. The proposed Schedule J would collect some information related to health care claims, but these are summary statistics,⁶ not the detailed information on payment and quality that APCDs collect on a per-encounter, per-provider basis. The APCD Council and representative States have worked on compiling an agreed-upon standard set of health care claim and related data that could be collected from all group

⁶ With respect to claims payment data, Schedule J proposes to collect: how many post-service benefit claims were submitted during the plan year, how many benefit claims were approved during the plan year, how many benefit claims were denied during the plan year, how many benefit claim denials were appealed during the plan year, how many appealed claims were upheld as denials, how many were payable after appeal, whether any claims for benefits were not adjudicated within the required timeframes, how many pre-service claims were appealed during the plan year, how many of those appeals were upheld during the plan year as denials and how many were approved during the plan year after appeal, and whether the plan was unable to pay claims at any time during the plan year and, if so, the number of unpaid claim, and the total dollar amount of claims paid during the plan year.

health plans—the Common Data Layout.⁷ We have included a comparison between the data elements to be reported under proposed Schedule J and relevant data elements in the Common Data Layout that could be used to address the topics outlined in Schedule J.⁸

Adding the submission of the Common Data Layout to Schedule J will improve the utility of Schedule J to meeting DOL’s stated objectives of improving plan transparency; conducting effective oversight over group health plan compliance; and making more information on health plan enrollment, claims, and health outcomes available to Federal and State regulators and the public.

The type of data collected by APCDs goes deeper than the data fields in Part IV of Schedule J (Health Benefit Claims Processing and Payment) and could improve DOL’s oversight. The elements in the Common Data Layout can be analyzed to provide DOL a much deeper understanding of group health plans’ claims processing and payment. For example, claims can be analyzed by type of service (e.g., inpatient, outpatient, pharmacy, etc.) to understand if there are variations in claims experience in populations that could be important for the oversight and policy functions described by DOL. Augmenting Schedule J with the information from the Common Data Layout would enable detailed analysis of these issues, particularly if DOL leverages the existing analytic infrastructure and experience of State APCDs to assist with this type of analysis.

Assessments of plan compliance using data to be reported in Part V of Schedule J (Compliance Information) would be particularly enhanced by the addition of the Common Data Layout elements and partnership with APCDs. While Schedule J as proposed simply requests yes/no responses for the evaluation of the compliance areas of interest, there are many areas that could be evaluated in much more depth using the Common Data Layout and APCDs’ analytic capacities. For example, for measures of compliance with ACA (Schedule J question 30), APCDs have the ability to measure rate of use of services across different plans (e.g., preventive care visits, which are a focus of the ACA), rather than limiting the understanding of adherence to the ACA service requirements as a simple attestation (e.g. dichotomous yes/no).

Health care claims and related data need to be collected more frequently than the annual data collection proposed in Schedule J. APCDs collect health care claims data monthly or quarterly, to allow for the provision of transparent cost information to the public, and to enable timely analysis of cost trends and other developments in health care markets. Monthly or quarterly reporting is important for reasons of assessing and improving data quality in a timely way that is not possible with an annual data submission. Additionally, more frequent reporting provides actionable information to users and policy makers, identifying use patterns and trends to guide policy and quality improvement interventions.

State APCDs could collect the Common Data Layout more frequently and could analyze and aggregate the information gathered under the Common Data Layout to be reported to DOL annually, assisting DOL and group health plans and administrators with annual data reporting of Schedule J elements.

B. Health care claims and related data from self-funded ERISA plans is integral to achieving the ACA’s objectives to oversee and improve the quality, cost, and transparency of health care.

DOL should authorize collection of health care claims and related data because the ACA aimed to expand oversight not only of group health plans’ fiduciary and financial decisions, but also to the quality and cost of the health care provided by plans. Health care claims data is the raw data that assists DOL to study and ascertain the quality and cost of care purchased by group health plans consistent with PHSA §§ 2715A and 2717. Importantly,

⁷ See Appendix B.

⁸ See Appendix C.

without DOL action, in many states there will be no way for regulatory authorities, researchers, the public, and millions of enrollees to access this critical data from self-funded group health plans following the *Gobeille* decision.⁹

Nationally, approximately 63% of all workers with employer-based health insurance are in self-funded plans.¹⁰ Moreover, the percentage of private employers offering a self-funded health plan has risen from 28.5% in 1996 to 39% in 2015 (a 36.8% increase).¹¹ The loss of such a large portion of an APCD's database can skew the data and may limit the accuracy of any policy analysis performed using the data. The data from self-funded plans may differ in systematic ways from other populations. For example, those who get their insurance through employers tend to be healthier than those covered by public payers,¹² and different industries, sizes of employers, and geographic regions have different rates of self-insurance, and thus estimates based on remaining data will under-count the health care needs and costs of industries/employers that tend to self-insure.¹³ Gathering comprehensive data from all group health plans is critical to conducting meaningful analysis of the ways in which health care cost, quality, and utilization differs between self-funded, fully insured, government, and other populations. Representatives of key associations of State executive and legislative officials have asserted that the "availability of data from both the insured and self-insured population is critically important to states for health care planning, public policy and economic development."¹⁴

Adding the Common Data Layout to the proposed Schedule J will address significant data gaps and implement the health care cost and quality transparency requirements of the ACA. DOL can use its authority to restore critical APCD data and leverage existing investments and infrastructure to facilitate both Federal and State health improvement initiatives.

Containing health care costs and improving health system performance requires the availability of comprehensive, local, encounter-specific data. Federal and State regulators as well as employer-sponsors of health plans can benefit from health care claim data reporting to understand the quality of care enrollees receive, how much variation there is in health care costs, and what opportunities exist to improve the health and health care of enrollees.

The examples below illustrate the ways APCD data are being used to promote oversight and transparency of health care costs, quality, and utilization.

- **Assessing geographic variations in price and utilization.** The Oregon Health Authority publishes quarterly reports that compare per-member per-month costs and utilization, by service category, for commercially

⁹ Brief for the United States, as Amicus Curiae Supporting Petitioner, *Gobeille v. Liberty Mutual Ins. Co.*, 577 U.S. ____ (2016) (No. 14-181).

¹⁰ Kaiser Family Foundation, *2015 Employee Health Benefits Survey*, Sept. 22, 2015, <http://kff.org/health-costs/report/2015-employer-health-benefits-survey/>.

¹¹ Paul Fronstin, *Self-Insured Health Plans: Recent Trends by Firm Size, 1996-2015*, 37 EMP. BENEFIT RES. INST. NOTES 2 (Jul. 2016).

¹² Brief for the Harvard Law School Center for Health Law & Policy et al., as Amici Curiae in support of Petitioner, *Gobeille v. Liberty Mutual Ins. Co.*, 577 U.S. ____ (2016) (No. 14-181), at 19-20.

¹³ Brief for the American Hospital Association & the Association of American Medical Colleges, as Amici Curiae in Support of Petitioner, *Gobeille v. Liberty Mutual Ins. Co.*, 577 U.S. ____ (2016) (No. 14-181), at 19.

¹⁴ Brief for the National Governors Association, National Conference of State Legislatures, Council of State Governments, National Association of Insurance Commissioners, and Association of State and Territorial Health Officials, as Amici Curiae in Support of Petitioner, *Gobeille v. Liberty Mutual Ins. Co.*, 577 U.S. ____ (2016) (no. 14-181), at 15.

insured, public employees, and public payers.¹⁵ Colorado uses its APCD to study price variation for common procedures among facilities.¹⁶ Maryland uses APCD data to compare the unit-costs, utilization, per-member per-month costs, out-of-pocket and insurance payments, geographic variations, and physician access data across geographic regions.¹⁷

- **Promoting cost and quality transparency and protecting consumers.** Both New Hampshire’s HealthCost and Maine’s CompareMaine websites provide provider-specific price and quality information to consumers, health plan enrollees, and employers to promote health care comparison shopping through cost- and quality-transparency tools.¹⁸ Both systems have historically included data from self-funded health plans to make these consumer tools available to enrollees of self-funded employee health plans.
- **Tracking health care spending drivers and trends.** Massachusetts used its APCD data to produce an annual report analyzing trends in health care spending for commercial payers by category of service, type of episode, and geographic area.¹⁹ Minnesota used its APCD data to analyze prescription drug spending by therapeutic category and setting (office-administered vs. pharmacy benefit).²⁰ Rhode Island released a report analyzing the top 15 clinical complaints and associated costs of potentially avoidable emergency room visits broken down by payer type.²¹
- **Promoting public health.** Organizations in Virginia and Utah have used APCD data to track opioid prescription claims across geographic areas and patient characteristics to understand and address trends in opioid use.²² New Hampshire used APCD data to measure access to and utilization of preventive services, such as cancer screening or diabetic testing and treatment, among its adult Medicaid population.²³

Our collective ability at the State and Federal level to understand and oversee the key drivers of health care spending and health outcomes—the prices paid and the quality of each episode of care—would be significantly

¹⁵ Oregon Health Authority, Leading Indicators for Oregon’s Health Care Transformation: Quarterly Data from the All-Payer, All-Claims Reporting Program (Sept. 25, 2015), <https://www.oregon.gov/oha/analytics/APACPageDocs/Leading-Indicators-Report-September-2015.pdf>.

¹⁶ Center for Improving Value in Health Care, Cost Driver Spot Analysis: Payment Variation by Payer, Feb. 2016, http://www.civhc.org/getmedia/118a37cb-2fc0-4896-abe2-1ffd251fbc3/2.2016_spot_analysis_paymentvariationbypayer.aspx/ (last visited, Sept. 6, 2016).

¹⁷ Maryland Health Care Commission, Costs, Utilization and Resources Transparency Initiative, <http://mhcc.maryland.gov/transparency/Default.html> (last visited Sept. 6, 2016).

¹⁸ NH HealthCost, <http://nhhealthcost.nh.gov/> (last visited Sept. 6, 2016); COMPAREMAINE, www.comparemaine.org (last visited Sept. 6, 2016).

¹⁹ Massachusetts Ctr. for Health Info. & Analysis & Health Pol’y Comm’n, Massachusetts Commercial Medical Care Spending: Findings from the All-Payer Claims Database 2010-2012, July 2014, <http://www.mass.gov/anf/docs/hpc/apcd-almanac-chartbook.pdf> (last visited Sept. 6, 2016).

²⁰ Minnesota Dep’t of Health, Prescription Drug Spending Trends in MN, Feb. 29, 2016, http://www.health.state.mn.us/healthreform/allpayer/20160229_rxtrends.pdf (last visited Sept. 6, 2016).

²¹ Rhode Island Dep’t of Health, Potentially Preventable Emergency Room Visits, <http://health.ri.gov/data/potentiallypreventableemergencyroomvisits/> (last visited Sept. 6, 2016).

²² Virginia Hospital & Healthcare Assn., Data Show Southwest Virginia Hard Hit by Opioid Crisis, Jan. 29, 2016, <http://www.vhha.com/research/2016/01/29/data-show-southwest-virginia-hard-hit-by-opioid-crisis/> (last visited Sept. 6, 2016); HealthInsight Utah, Transparency Advisory Group, April 19, 2016, <https://healthinsight.org/tools-and-resources/send/38-in-person-events/347-transparency-advisory-group-meeting-slides-april-19-2016> (last visited Sept. 6, 2016).

²³ New Hampshire Comprehensive Health Care Information System, *Adult Preventive Health Care in New Hampshire—Issue Brief*, June 2009, www.dhhs.nh.gov/ombp/documents/adultpreventivebrief.pdf.

compromised without health care claims data from self-funded group health plans. This data will remain almost totally inaccessible without DOL action for a large and significant segment of the market, and this is why DOL must act within its expansive authority to collect health care claims and related data from self-funded group health plans.

2. DOL has statutory authority to require self-funded group health plans to submit health care claims and related data.

A. PHSA §§ 2715A and 2717 and ERISA §§ 104 and 505 authorize DOL to collect health care claims and related data from group health plans

DOL has statutory authority to require reporting of health care claims and related data from ERISA plans under PHSA §§ 2715A and 2717, which were incorporated into ERISA and applied to group health plans by Section 715 of ERISA. In the *Gobeille* decision, the Supreme Court indicated that existing law could allow DOL to collect and share health care claims data from plans subject to ERISA, noting that beyond the current requirement of financial reporting under ERISA, the Secretary of Labor “has authority to establish additional reporting and disclosure requirements for ERISA plans.”²⁴

PHSA §§ 2715A and 2717 authorize additional data collection beyond that which DOL proposes to collect in Schedule J. Section 2715A authorizes DOL to collect information to improve the transparency of payments and costs from group health plans, including claims payment policies, financial disclosures, out-of-network payments, and “information as determined appropriate by the Secretary.”²⁵ This last element suggests Congress intended to grant broad discretion over the types of information gathered to promote transparency of health care payments and costs and is certainly broad enough to encompass health care claims data. Section 2717 authorizes the DOL to collect information needed to assess and monitor the quality of group health plans, including comprehensive quality reporting, care coordination, discharge and readmission information.

As noted by the Supreme Court in *Gobeille*, the Secretary of DOL has the authority under ERISA § 104(a)(2)(B) to “require[e] any information or data from any [plan] where he finds such data or information is necessary to carry out the purposes of the statute.”²⁶ DOL’s authority to request this additional information extends beyond the annual reporting requirements of Form 5500 and Schedule J.²⁷ Moreover, ERISA § 505 provides DOL with the broad authority to promulgate regulations as the Secretary “finds necessary or appropriate to carry out the provisions of this subchapter,” which includes the authority to prescribe forms and to provide for the keeping and inspection of books and records.²⁸

²⁴ *Gobeille v. Liberty Mutual Ins. Co.*, 136 S. Ct. at 944. The Court goes on to say that the Secretary of Labor “may be authorized to require ERISA plans to report data similar to that which Vermont seeks, though that question is not presented here.” 136 S. Ct. at 945.

²⁵ Section 2715A applies to group health plans the transparency and disclosure standards set forth in 42A U.S.C. § 18031(e). The “Secretary” in §18031(e) refers to the Secretary of HHS, not the Secretary of Labor. However, § 18031(e)(D), provides that with respect to group health plans, the “Secretary of Labor shall update and harmonize the Secretary’s rules concerning the accurate and timely disclosure to participants by group health plans of plan disclosure, plan terms and conditions, and periodic financial disclosure with the standards established by the Secretary under subparagraph (A).”

²⁶ 136 S. Ct. at 944 (internal quotations omitted).

²⁷ ERISA § 104(a)(2)(B), providing that nothing about the requirement for employee benefit plans to file annual reports shall preclude the Secretary from requiring data from plans that are necessary to carry out the purposes of ERISA.

²⁸ ERISA § 505.

Taken together, PHSA §§ 2715A and 2717 and ERISA §§ 104 and 505 provide ample statutory authority for DOL to collect health care claims and related data from group health plans. PHSA § 2715A authorizes collection of data on health care costs and payments and § 2717 authorizes collection of data on health care quality. The authority to evaluate and report on health care cost and quality for group health plans also includes the authority to collect the underlying raw data—the health care claims and related data—that enables these assessments of health care cost and quality. DOL also has authority to collect data under the provisions of ERISA §§ 104 and 505 which authorize DOL to promulgate regulations and require any information or data from plans as necessary to carry out the purposes of the statute. The health care cost and quality transparency and reporting purposes of PHSA §§ 2715A and 2717 were incorporated into ERISA by § 715, so DOL has the authority to require health care claims and related data from group health plans to carry out these purposes.

B. Compliance with annual reporting requirements, including Schedule J, should not be deemed to satisfy all group health plan obligations under PHSA §§ 2715A and 2717

Unless health care claims and related data are added as Part VI of Schedule J, the submission of Schedule J should not fully satisfy a plan’s reporting obligations under PHSA §§ 2715A and 2717.²⁹ DOL should preserve its ability to require that ERISA plans report additional data, as outlined in these comments, to further the goals of health care cost and quality transparency and oversight. Allowing annual completion of Schedule J as proposed to satisfy a group health plan’s reporting obligations under PHSA §§ 2715A and 2717 would impede any further requirement that self-funded plans submit health care claims and related data on a more frequent basis than annually.

We support DOL’s efforts to expand reporting by group health plans in the proposed rule and new Schedule J and agree it will “result in annual return/report forms that are a more effective policy, enforcement, and research tool, and one that will increase transparency, accountability, and confidence in the employee benefit plan system.”³⁰ However, if the Common Data Layout are not incorporated into Schedule J to be tested in States with APCDs, completion of Schedule J as proposed should not satisfy all reporting obligations under PHSA §§ 2715A and 2717 to allow room for additional health claims data collection.

3. Proposal for a Federal pilot program to collect standardized health care claims and related data in cooperation with State APCD

We propose that DOL use its authority under PHSA §§ 2715A and 2717 and ERISA §§ 104 and 505 to require as part of Schedule J that group health plans submit applicable data elements from a standardized health care claims dataset, the Common Data Layout,³¹ to be tested through a pilot program in collaboration with States with APCD data collection capacity. The adoption of a standardized dataset will minimize burden on ERISA plans and adhere to ERISA’s statutory goals of uniformity, consistent with the Supreme Court’s decision in *Gobeille*.

We further propose that DOL pursue a pilot approach and begin collecting the Common Data Layout in States with APCDs or similar data collection capacities in order to: (1) study the usefulness of health care claims data collection to the regulation of group health plans; (2) assess the efficacy of the Common Data Layout; (3) evaluate the technological systems needed to collect this data on a more widespread basis; and (4) preserve the federal government’s investment in States’ APCD efforts consistent with the ACA. DOL can accomplish this additional data

²⁹ 81 Fed. Reg. 47496, 47500 (“this document includes proposed conforming amendments in 29 CFR 2590.715-2715A and 29 CFR 2590.715-2717 to clarify that compliance with the proposed annual reporting requirements by plans subject to ERISA that provide group health benefits would satisfy the ACA reporting requirements under PHS Act sections 2715A and 2717 incorporated in ERISA through ERISA section 715(a)(1).”)

³⁰ 81 Fed. Reg. 47496, 47497 (Jul. 21, 2016).

³¹ See Appendix B.

collection with minimal additional expense and duplication of effort by partnering with State APCDs through cooperative agreements under ERISA 506.

State APCDs would collect the raw data elements contained in the Common Data Layout and annually report aggregated information drawn from the Common Data Layout to DOL as part of Schedule J reporting and analysis. Importantly for States, the APCDs would be able to use and share data from ERISA plans together with all other payers' data to further the policy, consumer protection, and research purposes for which APCDs were established.

To ensure that all data collection is consistent with ERISA and the *Gobeille* decision, we propose that DOL seek to:

- i. Adopt a uniform dataset, the Common Data Layout, from which all ERISA plans will report as part of Schedule J;³²
 - ii. Provide that self-funded ERISA plans are not required to report more data than required by the Common Data Layout;
 - iii. Enter into agreements with States or State-run APCDs to collect, store, and share the Common Data Layout; and
 - iv. Assure that the State's APCD operations include privacy and security protections for personally identifiable information.
- A. The adoption of a standardized health care claims dataset minimizes burden on DOL and ERISA plans and adheres to ERISA's statutory goals of uniformity.

ERISA's statutory goals of uniformity would be maintained because the data collected from group plans under our proposal would be standardized. Since the *Gobeille* decision was announced, the APCD Council, representative States, and other stakeholders have undertaken an intensive effort to establish the Common Data Layout, a uniform, standardized set of health care claims and related data elements, which could be used to collect applicable data elements from self-funded group health plans across various States and the Federal government.³³ To further minimize the burden on plan administrators and regulators, the Common Data Layout could be used for the submission of fully-insured plan data, as well as self-funded plan data. The use of the Common Data Layout by all payers and across States would represent a significant opportunity to achieve greater efficiency and effectiveness as well as lower costs for all parties.

The majority in *Gobeille* stated that “[p]reemption is necessary to prevent the States from imposing novel, inconsistent, and burdensome reporting requirements on plans.”³⁴ Our proposal is consistent with *Gobeille* because, for self-funded plans, the legal requirement to submit health care claims data would stem from DOL, not the various States, even while the States assist DOL with the data collection. The burden of reporting data in some States but not others for multi-state plans would be minimal because the substantive reporting requirements would be standardized.

- B. ERISA § 506 permits DOL to enter into cooperative agreements with States to achieve DOL's functions where it would reduce duplication and avoid unnecessary costs

³² See Appendix B.

³³ See Appendix B. States would continue to exercise regulatory authority over payers and health care claims data not subject to ERISA preemption, including the States' authority to engage in insurance regulation to collect data from fully insured group health and other State-regulated plans.

³⁴ 136 S. Ct. 936, 945 (2016).

ERISA § 506 authorizes DOL to work with States, State agencies, and other Federal agencies to collect this data, in part to “avoid unnecessary expense and duplication of functions among Government agencies.”³⁵ Eighteen states have passed laws creating APCDs, and the Federal government has also devoted significant grant funds to this effort under the ACA.³⁶

The most cost-effective approach for DOL to begin to collect health care claims and related data could be to capitalize on the existing capacity of States to collect and report this data. Data collection could be expanded over time through the addition of new State partners or a Federal data collection function for ERISA plans in States without data collection capacity.

Section 506 provides DOL broad and flexible authority to enter into cooperative agreements with States or State APCDs (and for that matter, coordinate with HHS or other Federal agencies) to collect applicable elements of the Common Data Layout from ERISA plans.³⁷ Such cooperative agreements entered into between DOL and States are explicitly exempted from ERISA preemption by ERISA § 514(b)(3), which provides, “Nothing in this section shall be construed to prohibit use by the Secretary of services or facilities of a State agency as permitted under section 1136 of this title.”

Partnering with States with capacities to collect the Common Data Layout will reduce the burden on health plans seeking to comply with Schedule J and allow for more comprehensive data from States to assist DOL and other federal agencies’ responsibilities under the law. Such collaboration between DOL and State APCDs will avoid duplication of effort and infrastructure, while streamlining efforts at the state and national level to provide meaningful information on health care cost, quality, utilization, compliance, and health care delivery reform.

Uniformity is not compromised by an incremental approach to health care claims and related data collection in partnership with existing State APCDs. Consistent with the Supreme Court’s opinion in *Gobeille*, the participation or assistance of State APCDs in federally authorized health care claims data collection would not impose additional State-specific duties upon self-funded group health plans and instead would establish a national, uniform data submission format.

³⁵ ERISA § 506 provides, in relevant part, “In order to avoid unnecessary expense and duplication of functions among Government agencies, the Secretary may make such arrangements or agreements for cooperation or mutual assistance in the performance of his functions under this subchapter and the functions of any such agency as he may find to be practicable and consistent with law. The Secretary may utilize, on a reimbursable or other basis, the facilities or services of any department, agency, or establishment of the United States or of any State or political subdivision of a State, including the services of any of its employees, with the lawful consent of such department, agency, or establishment; and each department, agency, or establishment of the United States is authorized and directed to cooperate with the Secretary and, to the extent permitted by law, to provide such information and facilities as he may request for his assistance in the performance of his functions under this subchapter.”

³⁶ PHSA § 2794, codified at 42 U.S.C. § 18031 (providing Federal assistance to States to establish the Exchanges); Social Security Act § 115A, codified at 42 U.S.C. § 1315a (establishing the Center for Medicare and Medicaid Innovation).

³⁷ Under ERISA § 506, this authority to enter into agreements or arrangements with States and State agencies is limited only by the requirement of State consent and that the arrangement be “consistent with law.” The requirement for state consent is consistent with the holding under *Printz v. United States*, that “the federal government may not compel the states to enact or administer a federal regulatory program.” The *Printz* holding, however, continues to allow the federal government to enter into cooperative agreements to which the states consensually agree to administer federal programs.

- C. The pilot program to test the collection of uniform health care claim data in collaboration with State APCDs could begin immediately, while the effective date for Schedule J reporting more generally could be delayed until plan year 2019.

The effective date of the proposed Schedule J is too late to address current delays in reporting to State APCDs. The proposed rule would go into effect for plan year 2019, but the States need data dating back to March 1, 2016, the date the *Gobeille* decision was announced and some ERISA plans stopped submitting health care claims and related data to APCDs.³⁸

States have assumed a significant role in providing oversight of health care use and spending and have built ongoing systems to provide oversight of health care costs and quality based on their ACPD data, and these efforts could be severely curtailed if data collection was suspended for three years until the effective date of the proposed Schedule J. For example, many of the quality measures collected by APCDs require two continuous years of data to calculate, and any gap in data will mean that APCDs will have to start the measurement process over again. In other words, if data collection for self-funded plans does not resume until January 2019, APCDs would be unable to incorporate and analyze health care claims and other related data from these plans until 2021. Because pilot programs could be implemented more swiftly than a widespread, national data reporting requirement, the pilot approach could address the States' need to fill the data gap created by *Gobeille* and to avoid a long period of missing data, which could cripple analysis and oversight efforts.

We propose that DOL begin the pilot program with willing States immediately to study the data collection under the Common Data Layout under Schedule J, while the effective date for Schedule J more generally can be delayed until plan year 2019. We understand that DOL and other agencies may require additional time to build and configure the EFAST2 or other electronic reporting systems. However, States with APCDs currently have the capacity to collect health care claims data and can work with DOL to test how best the States can reduce the burden on health plans or administrators with Schedule J reporting obligations and how States can reduce duplication and assist DOL's own data collection needs.

- D. ERISA § 513 authorizes DOL to do pilot studies to test the usefulness and technological resources needed to collect health care claims and related data

DOL need not engage in widespread data collection nationally. Rather, DOL has the flexibility to pursue an incremental approach under its statutory authority to implement pilot studies in partnership with States that have the capacity to collect health care claims and related data through State APCDs or otherwise. ERISA § 513 provides DOL statutory authority to engage in pilot programs to test collection of additional health care claim and related data pursuant to its power to undertake research, studies and reports.³⁹ Health care claims data is the raw data about the cost and quality of health care that group health plans provide to enrollees and is thus clearly encompassed in the broad grant of authority to "collect, compile, analyze . . . data . . . relating to employee benefit plans."

Under the statutory authority provided in ERISA § 513 to undertake research, surveys, and studies, there is no obligation for DOL to immediately require collection of data from ERISA plans across all States. The authority to engage in research, surveys, and studies carries with it the strong implication that DOL could engage in pilot

³⁸ If retroactive data reporting is not possible, states propose discussions with DOL to explore alternatives for filling the gap in self-funded data.

³⁹ ERISA § 513 provides, in relevant part, "The Secretary is authorized to undertake research and surveys and in connection therewith to collect, compile, analyze and publish data, information, and statistics relating to employee benefit plans, including retirement, deferred compensation, and welfare plans, and types of plans not subject to this chapter."

programs. In subsection 513(a)(4), ERISA provides that the studies “may be conducted directly, or indirectly through grant or contract arrangements.”⁴⁰ Studies and surveys are often conducted on samples or subsets of data, through contract with States or other third parties who may be in a position to gather subsets of data.

Nor would it be arbitrary or capricious or an abuse of discretion for DOL to pursue an incremental approach as a policy matter.⁴¹ DOL has substantive justifications for pursuing an incremental approach if it so chooses, including the need to marshal finite Departmental resources and the appropriateness of a pilot approach to test what types of information about ERISA plans can be elucidated by the data analysis coming from the States, how cooperative agreements with State entities can best work in this context, the efficacy of the Common Data Layout, and how to capitalize on existing State APCDs, including those supported by the Center for Medicare and Medicaid Innovation under the ACA, created to test methods of improving health care quality and cost containment among all payers, including public payers and group health plans.⁴²

In sum, DOL has authority to pursue health care claims and related data collection from group health plans using an incremental, pilot approach in coordination with State APCDs. We propose that DOL seek to establish a standardized set of health care claims data, the Common Data Layout, to be collected as part of Schedule J from group health plans by partnering with States that have APCDs or develop them in the future. The pilot program would utilize existing State infrastructure and thus could begin immediately, while the effective date of Schedule J more generally could be delayed until the necessary Federal/DOL data systems are established. This collaborative arrangement between DOL and State APCDs would provide continued access to this critical information while allowing DOL to leverage the expertise and existing infrastructure of the State-run APCDs and pilot the Common Data Layout. Doing so would be consistent with DOL’s statutory authority under ERISA, the majority’s opinion in *Gobeille*, and DOL’s obligations under the Administrative Procedure Act.

⁴⁰ ERISA § 513(a)(4).

⁴¹ Administrative Procedure Act, 5 U.S.C. § 706(2)(A).

⁴² 42 U.S.C. § 1315a.

Appendix A

Model preamble and rule text for the collection of health care claims data from self-funded ERISA plans

Background

Earlier this year, the U.S. Supreme Court’s decision in *Gobeille v. Liberty Mutual*⁴³ dealt a blow to the 18 existing state-run all-payer claims databases (APCDs) by holding that the Employment Retirement Income Security Act of 1974 (ERISA) preempts Vermont’s all-payer claims data reporting law with respect to self-funded employer health benefit plans. In response to the Court’s decision, a number of state APCDs and/or payers have temporarily halted health insurance claims submission from plans as both groups determine how data reporting will now be done.

Importance of APCDs and Comprehensive Claims Data

Without prompt action, the *Gobeille* ruling could severely diminish ongoing efforts to use claims databases to support important public policy efforts and to increase the transparency of medical costs.

States, employers, and individuals all face tremendous challenges related to health care, with ever-increasing costs being felt most acutely. Decisions about the future of health care require accurate data that reflect the experience of a wide range of health care users. Historically, this type of information has been almost impossible to collect and utilize. In response to past data challenges, many States have developed APCDs that compile information across payers and make data accessible in a way that allows for informed decision-making.

APCDs are essential to a wide range of health reform efforts including public reporting of health care costs, rate reviews, and initiatives that leverage data to address health care cost drivers.

The setback caused by the *Gobeille* decision and the loss of self-funded insurer data seriously hampers the work of APCDs. The usefulness of APCDs depends on inclusion of the largest possible number of claims. A recent Kaiser Family Foundation survey reported that approximately 63% of workers offered coverage through their employer were enrolled in plans that were either partially or completed self-funded.⁴⁴

Legal Authority for Department of Labor Rulemaking

In the *Gobeille* decision, the Supreme Court indicated that existing law could allow the United States Department of Labor (the Department) to collect and share health care claims data from plans subject to ERISA. The Court’s majority opinion notes that, beyond the current requirement of financial reporting under ERISA, the Secretary of Labor “has authority to establish additional reporting and disclosure requirements for ERISA plans.”⁴⁵

ERISA’s provisions allow the Secretary of Labor to (1) to collect additional quality and cost-related information from group health plans under the Public Health Service Act, incorporated into ERISA by the Patient Protection and Affordable Care Act (ACA); (2) to promulgate regulations and require data and information from ERISA plans where necessary to carry out the purposes of the statute;⁴⁶ (3) to partner with states to perform Department functions

⁴³ *Gobeille v. Liberty Mutual Ins. Co.*, 136 S. Ct. 936 (2016), http://www.supremecourt.gov/opinions/15pdf/14-181_5426.pdf

⁴⁴ Kaiser Family Foundation, 2015 Employer Health Benefits Survey, Sept. 22, 2105, <http://kff.org/health-costs/report/2015-employer-health-benefits-survey/>. This percentage includes a small subset of workers enrolled in government self-insured health plans that by law are exempt from ERISA’s framework.

⁴⁵ *Gobeille v. Liberty Mutual Ins. Co.*, 136 S. Ct. at 944.

⁴⁶ ERISA §104(a)(2)(B), 29 U.S.C. § 1024; ERISA § 505, 29 U.S.C. § 1135.

when doing so would prevent unnecessary expense and duplication;⁴⁷ and (4) to use his or her authority to undertake research and surveys, which includes the ability to collect and compile data, information, and statistics from self-funded employee benefit plans.⁴⁸

Entering into cooperative agreements with States to collect claims data would assist the Department to fulfill its statutory duties under ERISA and the ACA. Reports and analyses generated from claims data in participating States could be used to evaluate how those plans manage costs, inform the Department’s reports to Congress on self-funded plans,⁴⁹ and enforce the ACA’s insurance market reforms applicable to group health plans,⁵⁰ including enhancing plan transparency to enrollees.⁵¹ Such collaboration with states would be consistent with Congress’ support for the establishment of State APCDs through the Center for Medicare and Medicaid Innovation to test innovative payment models to reduce health care costs and improve quality.⁵²

Significantly, as the Federal government identified in its amicus brief for *Gobeille*, if the Department does not to step in and support data collection from self-funded plans, the Court has created a new ERISA vacuum in a critically important area of health care regulation.

Model Rule Text

- (a) *Basis and scope.* Section 715 of the Employee Retirement Income Security Act of 1974, as amended (hereinafter, the Act), as amended by the Patient Protection and Affordable Care Act, applies certain health insurance market reforms to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans, including the provision of additional information (Public Health Service Act, 42 U.S.C. § 300gg-15a) and quality reporting (Public Health Service Act, 42 U.S.C. § 300gg-17). Sections 104(a)(2)(B) and 505 of the Act, authorize the Secretary of Labor to promulgate regulations and require data and information from ERISA plans where necessary to carry out the purposes of the statute. Under section 506 of the Act, the Secretary may enter into cooperative agreements with any department, agency, or establishment of the United States or of any State or political subdivision of the State to perform the functions of the Secretary under the Act. This section sets forth provisions for the Secretary to study the usefulness of the collection of and best practices for database management for health care claim and associated data from group health plans and health insurance issuers providing health insurance coverage in connection with group health plans in coordination with qualified entities designated by the Secretary through cooperative agreements.
- (b) *Definitions.* As used in this section, the definitions in § 2590.701-2 and the following definitions apply:
- (1) *Health care claim and associated data* means the standardized data elements described in Appendix B, as may be updated by the Secretary, relating to medical care provided by group health plans and health insurance issuers providing health insurance coverage in connection with group health plans.
- (2) *Qualified data entity* means a department, agency, or establishment of the United States or of any State or political subdivision of the State that—
- (A) enters into a cooperative agreement with the Secretary to collect, receive, and use health care and associated claims data in one or more geographic areas to evaluate

⁴⁷ ERISA § 506, 29 U.S.C. § 1136.

⁴⁸ ERISA § 513(a)(1), 29 U.S.C. § 1143(a)(1).

⁴⁹ 42 U.S.C § 18013.

⁵⁰ ERISA § 715, 29 U.S.C. § 1185d.

⁵¹ PHSA § 2715A; 42 U.S.C. § 18031(e)(3).

⁵² 42 U.S.C. § 1315a.

the quality, cost, utilization, and supply of medical care provided by group health plans and health insurance issuers providing health insurance coverage in connection with group health plans;

- (B) agrees to abide by applicable privacy and security protections for the health care claim and associated data as the Secretary may specify; and
 - (C) with regard to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans, agrees to collect and use the health care claim and associated data and such other data elements as may be approved by the Secretary.
- (c) *Designation of qualified data entities.* The Secretary may enter into cooperative agreements with qualified data entities authorizing the qualified data entity to collect, receive, and use health care claim and associated data for one or more specified geographic areas. Qualified data entities shall share and transmit to the Secretary such health care claim and associated data, summary or statistical reports, or other information requested by the Secretary to study and assess the usefulness of such data collection to effectuate the Secretary's functions under the Act.
- (d) *Submission of health care claim and associated data.* Upon designation of a qualified data entity by the Secretary, the administrator of a group health plan and the health insurance issuer providing health insurance coverage in connection with a group health plan shall submit to the qualified data entity all health care claim and associated data relating to the geographic area or areas covered by the qualified data entity.
- (e) *Timing of data submission.* Beginning on January 1, 2017, the administrator of a group health plan and the health insurance issuer providing health insurance coverage in connection with group health plans shall furnish to the qualified data entity health care claims and associated data according to the schedule of submission specified by the Secretary. A qualified data entity may request submission of health care claim and associated data for any time period or periods beginning on January 1, 2016.
- (f) *Rejected submission.* The qualified data entity may reject and may require resubmission of any health care claim and associated data submitted under this section if the qualified data entity determines the submission incomplete.

Appendix B
The Common Data Layout: Standardized Health Care Claim and Related Data Elements
(Working Review Version as of September 20, 2016)

The following document summarizes the data elements contained in the Common Data Layout, standardizing the health care claim and related data that are currently collected by State APCDs and reducing the burden on data reporters. Specifications for data submission are under review by various stakeholder groups. Updates and a more detailed description of the Common Data Layout can be found at: www.apcdcouncil.org.

E. Eligibility File Data Elements

- Data Payer Code
- Plan ID
- Member Insurance Type Code/Product
- Start Year of Submission
- Start Month of Submission
- Insured Group or Policy Number
- Coverage Level Code
- Subscriber Social Security Number
- Plan Specific Contract Number
- Sequence Number
- Member Social Security Number
- Individual Relationship Code
- Subscriber Last Name
- Subscriber First Name
- Subscriber Middle Initial
- Member Last Name
- Member First Name
- Member Middle Initial
- Member Gender
- Member Date of Birth
- Member City Name
- Member County
- Member Country Code
- Member State or Province
- Member ZIP Code
- Member Street Address
- Member Race
- Member Ethnicity
- Member Hispanic Indicator
- Primary Insurance Indicator
- Medical Coverage under this plan (flag)
- Prescription Drug Coverage under this plan (flag)
- Dental Coverage under this plan (flag)
- Behavioral Health Coverage under this plan (flag)
- Coverage Type

- Plan State
- Market Category Code
- Special Coverage (this is for state specific codes---should we include this here?)
- Group Name
- Data Submitter Code
- Employer Name
- Employer Zip Code (Situs)
- Employer Tax ID
- NPI of Member's Elected PCP
- Member PCP Effective Date
- Member PCP Termination Date
- Plan Effective Date
- Plan Term Date
- HIOS Plan ID
- Metal Tier
- Market Segment
- Medical Home Indicator
- Medical Home NPI
- Purchased through public Health Insurance Exchange (flag)
- Last Activity Date
- Member's North American Industry Classification System (NAICS) Code
- Carrier Specific Unique Member ID
- Carrier Specific Unique Subscriber ID
- NAIC ID
- Employment Status of member/subscriber
- High Deductible Plan Indicator
- Total Monthly Premium Amount or Premium Equivalent
- Actuarial Value
- Grandfathered Plan Indicator
- Cost-Sharing Reduction Indicator
- Administrative Service Fees---Payers say this they don't have
- State Subsidy
- Plan Tier
- Tiered Network
- Plan Name

F. Medical File Data Elements

- Data Payer Code
- Data Submitter Code
- Plan ID
- Claim Filing Indicator Code
- Payer Claim Control Number
- Claim line counter
- Version number
- Cross Reference Claims ID
- Insured Group or Policy Number
- Subscriber Social Security Number
- Carrier Specific Unique Subscriber ID

- Subscriber Last Name
- Subscriber First Name
- Subscriber Middle Initial
- Plan Specific Contract Number
- Individual Relationship Code
- Member Sequence Number
- Member Social Security Number
- Carrier Specific Unique Member ID
- Patient Control Number
- Member Gender
- Member Date of Birth
- Member Last Name
- Member First Name
- Member Middle Initial
- Member Street Address
- Member City Name
- Member State or Province
- Member ZIP Code
- Paid Date
- Admission Date
- Admission Hour
- Admission Type
- Point of Origin
- Discharge Hour
- Discharge Status
- Rendering Provider ID
- Rendering Provider Tax ID Number
- Rendering Provider NPI
- Rendering Provider Entity Type Qualifier
- Rendering Provider First Name
- Rendering Provider Middle Name
- Rendering Provider Last Name or Organization Name
- Rendering Provider Suffix
- Rendering Provider Specialty
- Rendering Provider City Name
- Rendering Provider Street Address
- Rendering Provider State or Province
- Rendering Provider ZIP Code
- Billing Provider Number
- Billing Provider NPI
- Billing Provider Last Name or Organization Name
- Referring Provider NPI
- Attending Provider NPI
- Type of Bill – Institutional
- Place of Service – Professional
- Claim Status
- Type of Claim

- Diagnoses (Principal, Admitting, Other diagnoses, Reason for Visit, External Cause of Injury,)
- Present on Admission indicators
- Revenue Codes
- Procedure Codes
- Procedure Modifiers
- ICD-9/10-CM Procedure Codes (Principal and other)
- Dates of Service
- Quantity
- Quantity value
- Charge Amount
- Paid Amount
- Fee for Service Equivalent Amount
- Co-Pay Amount
- Coinsurance Amount
- Deductible Amount
- COB/TPL Amount
- Allowed Amount
- Other Insurance Paid Amount
- Discharge Date
- Diagnosis Related Group (DRG)
- DRG Version
- Ambulatory Payment Classification (APC)
- APC Version
- Drug Code
- Carrier Associated with Claim
- Practitioner Group Practice
- In Plan Network Indicator
- Payment Arrangement Type
- Denied Flag
- Denial Reason
- EPSDT Indicator
- Pay to patient flag

G. Pharmacy File Data Elements

- Data Payer Code
- Data Submitter Code
- Plan ID
- Carrier Associated with Claim
- Insurance Type/Product Code
- Payer Claim Control Number
- Claim line counter
- Version number
- Cross Reference Claims ID
- Insured Group or Policy Number
- Plan Specific Contract Number
- Subscriber Social Security Number

- Carrier Specific Unique Subscriber ID
- Subscriber Last Name
- Subscriber First Name
- Subscriber Middle Initial
- Plan Specific Contract Number
- Individual Relationship Code
- Member Sequence Number
- Member Social Security Number
- Carrier Specific Unique Member ID
- Patient Control Number
- Member Gender
- Member Date of Birth
- Member Last Name
- Member First Name
- Member Middle Initial
- Member Street Address
- Member City Name
- Member State or Province
- Member ZIP Code
- Paid Date
- Pharmacy ID
- Pharmacy Tax ID Number
- Pharmacy Name
- Pharmacy NPI
- Pharmacy Location City
- Pharmacy Location State
- Pharmacy ZIP Code
- Pharmacy Location Street Address
- Pharmacy Country Name
- Claim Status
- Drug Code (NDC)
- Drug Name
- New Prescription or Refill
- Generic Drug Indicator
- Formulary Indicator
- Dispensed as Written Code
- Compound Drug Indicator
- Date Prescription Filled
- Quantity Dispensed
- Drug Unit of Measure
- Days' Supply
- Charge Amount
- Paid Amount
- COB Amount
- Member Self-Pay Amount
- Sales Tax Amount
- Other Insurance Paid Amount

- Ingredient Cost/List Price
- Postage Amount Claimed
- Dispensing Fee
- Co-Pay Amount
- Coinsurance Amount
- Deductible Amount
- Allowed Amount
- Prescribing Physician ID
- Prescribing Physician First Name
- Prescribing Physician Middle Name
- Prescribing Physician Last Name
- Prescribing Physician NPI
- Prescribing Physician DEA Number
- Script Number
- Mail-Order Pharmacy Indicator
- In Plan Network Indicator
- Denial Reason

H. Dental File Data Elements

- Data Payer Code
- Data Submitter Code
- Plan ID
- Carrier Associated with Claim
- Claim Filing Indicator Code
- Payer Claim Control Number
- Claim line counter
- Version number
- Cross Reference Claims ID
- Insured Group or Policy Number
- Plan Specific Contract Number
- Subscriber Social Security Number
- Carrier Specific Unique Subscriber ID
- Subscriber Last Name
- Subscriber First Name
- Subscriber Middle Initial
- Plan Specific Contract Number
- Individual Relationship Code
- Member Sequence Number
- Member Social Security Number
- Carrier Specific Unique Member ID
- Patient Control Number
- Member Gender
- Member Date of Birth
- Member Last Name
- Member First Name
- Member Middle Initial
- Member Street Address
- Member City Name

- Member State or Province
- Member ZIP Code
- Paid Date
- Rendering Provider ID
- Rendering Provider Tax ID Number
- Rendering Provider NPI
- Rendering Provider Entity Type Qualifier
- Rendering Provider First Name
- Rendering Provider Middle Name
- Rendering Provider Last Name or Organization Name
- Rendering Provider Suffix
- Rendering Provider Specialty
- Rendering Provider City Name
- Rendering Provider State or Province
- Rendering Provider ZIP Code
- Place of Service – Professional
- Billing Provider Number
- Billing Provider NPI
- Billing Provider Last Name or Organization Name
- Service Provider Street Address
- Practitioner Group Practice
- Claim Status
- CDT Code
- Procedure Modifiers
- Dates of Service
- Charge Amount
- Paid Amount
- Co-pay Amount
- Allowed Amount
- Coinsurance Amount
- Deductible Amount
- Tooth Number or Letter
- Dental Quadrant
- Tooth Surface
- ICD-CM Diagnosis Code

I. Provider File Data Elements

- Data Payer Code
- Plan ID
- Provider ID
- Provider Tax ID
- Provider Entity
- Provider First Name
- Provider Middle Name or Initial
- Provider Last Name or Organization Name
- Provider Suffix

- Provider Specialty's
- Provider Office Street Address
- Provider Office City
- Provider Office State
- Provider Office Zip
- Provider DEA Number
- Provider NPI
- Provider State License Number
- Group Practice / Hospital System
- Data Submitter Code
- Entity type
- Atypical Provider Taxonomy Code
- Rendering Provider Country Name
- Rendering Provider County Name
- Rendering Provider Phone
- Rendering Provider Medicare Provider ID
- Rendering Provider Medicaid Provider ID

National Academy for State Health Policy
Appendix C

| Crosswalk Schedule J - CDL | | |
|---|--|--------------------------|
| Schedule J | CDL Field Name | CDLField ID# (reference) |
| Name of plan | Plan Name | ME933 |
| Three-digit plan number | Insured Group or Policy Number | ME006 (also in MC006) |
| Plans sponsor name | Group Name | ME032 |
| Employer Identification Number (EIN) | Employer Tax ID | ME919 |
| Part 1 - Group Health Plan Characteristics | | |
| 1 Approximate number of persons (including participants, beneficiaries and dependents of participants) covered under the plan at the end of the plan year? | Sum of unique Member ID (from eligibility) for that Insured Group or Policy Number (ME006) | |
| 2 The plan offers health coverage to the following: (check all that apply): employees, spouses, children, retirees, retirees only | | |
| 3 Indicate which of the following types of benefits and design characteristics are included under the plan (check all that apply): med/surg, mental health/substance use disorder benefits, pharmacy, wellness program, preventive care service, pregnancy services, vision, dental | Any members of that Group Policy Number with ME018 = medical coverage; ME019 = pharmacy coverage; ME020 = dental coverage; ME909 = behavioral health coverage | |
| 4 Health funding and benefit arrangement (check all that apply): health insurance issuer, benefits paid from general assets of the employer, trust | Not Available from CDL | |
| 5 Check all that apply to the plan: one or more benefit package options claiming grandfathered status under the Affordable Care Act, high deductible health plan, health reimbursement arrangement (HRA) or plan includes an HRA, health flexible spending account (FSA) or plan includes an FSA | Number of members with High Deductible Plan Indicator (ME922) = 1 (Yes); Grandfathered Plan Indicator (ME926) = 1 (grandfathered) ; no fields related to HRA or FSA | |
| 6a How many persons were offered COBRA benefits during the year? | Not Available from CDL | |
| 6b Of the persons counted in line 6a, how many persons elected COBRA benefits? | Number of members with Coverage Type (ME029) = STN (Short-term non-renewable health insurance. (e.g. COBRA) | |
| 6c How many persons were receiving coverage under the plan through COBRA during the plan year? | | |
| 7a Did the plan or plan sponsor receive any rebates, reimbursement or refunds other than those reported on Schedule A from service providers during the plan year? (yes/no) | Not Available from CDL | |
| 7b(1) If yes in 7(a), enter amounts of rebates, reimbursements, etc; and (2) type of service provider that provided each rebate, reimbursement, or refund (health insurance issuer, TPA, PDM, other); and (3) how each rebate, reimbursement, or refund was used (amount returned to participants, premium holiday, payment of benefits, other) | Not Available from CDL | |
| 8a If any benefits were provided pursuant to an insurance policy that was not reported on Schedule A, were there any premium payment delinquencies for premiums due but unpaid during the year? (yes/no) | Not Available from CDL | |
| 8b if yes in 8(a), indicate whether any premium delinquency resulted in a lapse in coverage (yes/no) | Not Available from CDL | |
| Part II - Service Provider and Stop Loss Insurance Information | | |
| 9a TPA Name, address, telephone number | | |
| 9b TPA EIN | | |
| 9c TPA NAIC NPN | | |
| 9d If TPA are being provided to the plan through a prototype/off-the-shelf ASO arrangement, enter the identification number of such insurance product | | |
| 10a Mental Health Benefits Manager Name, address, telephone number | | |

National Academy for State Health Policy

Appendix C

| | | |
|--|--|-------|
| 10b Mental Health Benefits Manager EIN | | |
| 10c Mental Health Benefits Manager NAIC NPN | | |
| 11a Substance Use Disorder Benefits Manager Name, address, telephone number | | |
| 11b Substance Use Disorder Benefits Manager EIN | | |
| 11c Substance Use Disorder Benefits Manager NAIC NPN | | |
| 12a Pharmacy Benefits Manager Name, address, telephone number | | |
| 12b Pharmacy Benefits Manager EIN | | |
| 12c Pharmacy Benefits Manager NAIC NPN | | |
| 13a Independent Review Organization Name, address, telephone number | Not Available from CDL | |
| 13b Independent Review Organization EIN | Not Available from CDL | |
| 13c Independent Review Organization NAIC NPN | Not Available from CDL | |
| 14a Wellness Program Manager Name, address, telephone number | Not Available from CDL | |
| 14b Wellness Program Manager EIN | Not Available from CDL | |
| 14c Wellness Program Manager NAIC NPN | Not Available from CDL | |
| 15 Was there a stop loss policy associated with the plan's obligation to pay health benefits? | Not Available from CDL | |
| Part III - Financial Information (Plans that Complete Schedule H, skip to Part IV) | | |
| 16 Contributions received during the plan year or receivable as of end of plan year (employer contributions received, employer contributions receivable, participant contributions received, participant contributions receivable, other contribution received or receivable, total contributions) | Not Available from CDL | |
| 17 Was there a failure to transmit to the plan any participant contributions or repayments as of the earliest date on which such contributions can reasonable be segregated from the employers general assts described in 29 CFR... (yes/no) | Not Available from CDL | |
| Part IV - Health Benefit Claims Processing and Payment | | |
| 18a enter the number of post-service benefit claims submitted during the plan year | Total number of claims submitted | |
| 18a (1) How many of those claims were approved during the plan year? | Total number of claims submitted and paid (?) where Claim Status (MC028) = 1, 2, or 3 (paid as primary, secondary or tertiary) | MC028 |
| 18a (2) How many of those claims were denied during the plan year? | Total number of claims submitted and denied where Claim Status (MC028) = 4 (denied) | MC028 |
| 18a (3) How many of those claims were pending at the end of the plan year? | Total number of claims submitted and pending where Claim Status (MC028) = 5 (pending) or 9 (pending - under investigation) as of September 30 (?)of year | MC028 |
| 18b Enter number of post-service benefit claim denials appealed during the plan year | Not available from CDL | |
| 18b (1) how many of those appeals were upheld during the plan year as denials? | Not available from CDL | |
| 18b (2) how many of those appeals were overturned and approved during the plan year after appeal? | Not available from CDL | |
| 18c Enter the number of pre-service benefit claims appealed during the plan year | Not available from CDL | |
| 18c (1) how many of those appeals were upheld during the plan year as denials? | Not available from CDL | |
| 18c (2) how many of those appeals were approved during the plan year after approval? | Not available from CDL | |
| 19 Were there any claims or appeals of adverse benefit determinations that were not adjudicated within the required timeframes? | Not available from CDL | |
| 19 (1) Number of claims | Not available from CDL | |
| 19 (2) Number of appeals | Not available from CDL | |
| 20 Did the plan fail to pay any claims during the plan year within one month of being approved for payment? | Not available from CDL | |

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Appendix C

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|---|------------------------|--|
| 20 (1) number of claims not paid within 1 month | Not available from CDL | |
| 20 (2) total amount not paid within one month | Not available from CDL | |
| 20 (3) number of claims not paid within 3 months or longer | Not available from CDL | |
| 21 Total dollar amount of benefits paid pursuant to claims during the plan year | Not available from CDL | |
| Part V - Compliance Information (Plans that file the Form M-1, skip questions 24 - 30) | | |
| 22a Were all plan assets held in trust, held by an insurance company qualified to do business in a State, or as insurance contracts or policies issued by such an insurance company? | Not available from CDL | |
| 23 Are the plan's summary plan description, including any summary descriptions of modifications, and summary of benefits and coverage in compliance with the applicable content specifications? | Not available from CDL | |
| 24 Is the coverage provided by the plan in compliance with the provisions of HIPAA of 1996, as incorporated in ERISA, and the Department's regulations thereunder? | Not available from CDL | |
| 25 Is the coverage provided by the plan in compliance with the provisions of Title I of the Genetic Information Nondiscrimination Act of 2008 as incorporated in ERISA and the Department's regulations thereunder? | Not available from CDL | |
| 26 Is the coverage provided by the plan in compliance with the Mental Health Parity Act of 1996 and the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 and the Department's regulations thereunder? | Not available from CDL | |
| 27 Is the coverage provided by the plan in compliance with the Newborns and Mothers' Health Protection Act of 1996 and the Department's regulations thereunder? | Not available from CDL | |
| 28 Is the coverage provided by the plan in compliance with the Womens Health and Cancer Rights Act of 1998? | Not available from CDL | |
| 29 Is the coverage provided by the plan in compliance with Michelle's Law? | Not available from CDL | |
| 30 Is the coverage provided by the plan in compliance with the Affordable Care Act and the Department's regulations issued thereunder? | Not available from CDL | |
| 31a Was the plan subject to the Form M-1 filing requirements during the plan year? | Not available from CDL | |
| 31b Is the plan currently in compliance with the form M-1 filing requirements? | Not available from CDL | |
| 31c Enter the Receipt Confirmation Code for the 20XX Form M-1 annual report | Not available from CDL | |