

**STATE ALL PAYER CLAIMS DATABASES ADVISORY COMMITTEE
REPORT WITH RECOMMENDATIONS UNDER SECTION 735 OF THE EMPLOYEE
RETIREMENT INCOME SECURITY ACT OF 1974**

BACKGROUND

This Report with recommendations was produced by the State All Payer Claims Databases Advisory Committee (SAPCDAC or Committee). The SAPCDAC was convened in 2021 as directed by section 735 of the Employee Retirement Income Security Act of 1974 (ERISA) (as added by section 115(b) of the No Surprises Act, enacted as part of the Consolidated Appropriations Act 2021, div. BB, tit. I, P.L. 116-260 (Dec. 27, 2020)). The Committee is governed by the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. App. 2.

Under ERISA section 735, the SAPCDAC is charged with advising the Secretary of Labor regarding the standardized reporting format for the voluntary reporting by group health plans to State All Payer Claims Databases. Reporting will include medical claims, pharmacy claims, dental claims, and eligibility and provider files collected from private and public payers. The statute directs the Committee to advise the Secretary on what guidance is necessary to provide to States on the process by which States may collect such data in the standardized reporting format. The Committee must submit a report to the Secretary, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce and the Committee on Education and Labor of the House of Representatives that includes recommendations on the establishment of the format and guidance. In accordance with section 735(e) of ERISA, the Committee remains in existence from the time of its convention until it submits its recommendations to the Secretary of Labor; the Senate Committee on Health, Education, Labor, and Pensions; the House Committee on Energy and Commerce; and the House Committee on Education and Labor.

The Committee is pleased to provide this report and its recommendations to the Secretary of Labor, Martin J. Walsh, as required under ERISA section 735 as added by section 115 of the *No Surprises Act*, enacted in December 2020. The Committee hopes that these recommendations prove useful to Secretary Walsh, the Department of Labor (DOL), the Department of Health and Human Services (HHS), and other stakeholders interested in supporting the collection and analysis of all-payer health care claims data at the state level with the goal of improving the quality and affordability of health care in the United States.

The primary focus of these recommendations, as outlined in ERISA section 735, is to guide Secretary Walsh in developing a standardized reporting format for the voluntary reporting by self-funded group health plans to State All Payer Claims Databases (APCDs), and to help in developing guidance to States on the process by which States may collect data from such plans.

Additionally, the Committee's recommendations include longer-term recommendations that Secretary Walsh and other health agency leadership may wish to consider to strengthen the path toward actionable data and effective data-driven health care transformation.

Members of the SAPCDAC are experts from a wide range of backgrounds, including data science, research, State APCDs, national data organizations, consumer organizations, key Federal agencies, and large self-funded employers. In developing these recommendations, the SAPCDAC received written and oral testimony from many interested parties, including legal and policy experts.

The scope of this report relates to encouraging self-funded plan sponsors to provide data to state all payer claims databases in a manner that is consistent with data that State APCDs collect from fully insured plans, some self-funded plans, Medicare, and Medicaid. Although existing State APCDs vary in their operations, use of data, and public reporting, there is an opportunity to create efficiencies among existing and newly formed State APCDs by improving the alignment of certain operational areas such as data collection and managing data privacy and security. The Committee's recommendations are intended to support the business case for additional self-funded plans to provide data, while also seeking to reduce any administrative burden on them through common operational processes.

There are many aspects of APCD processes that could be considered and standardized. Due to time constraints and the desire to expeditiously submit these recommendations to Secretary Walsh, this Report specifically focuses on four key areas: standardized data layout, the data submission process, data privacy and security concerns, and voluntary data submission processes.

ADVISORY COMMITTEE

As directed by the statute, the Advisory Committee is composed of 15 members. The Advisory Committee members are:

Maureen Mustard, MBA, Director of Health Analytics, New Hampshire Insurance Department –
Committee Chair

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IMPORTANCE OF HEALTH CARE DATA

According to a report from the Commonwealth Fund,¹ the United States spends nearly twice as much as other wealthy nations to provide health care, but our outcomes often are much worse than that of other nations. While, our health care system underperforms those in other nations, our health care costs continue to escalate much faster than our paychecks and overall inflation. According to the Kaiser Family Foundation,² between 2010 and 2020, average family premiums in the U.S. increased 55%, at least twice as fast as wages (27%) and inflation (19%). Moreover, as the COVID-19 pandemic has brought so clearly into focus, entire populations – particularly people of color, immigrant communities, and rural communities – experience significant health inequities and disparities.

Access to comprehensive health care data is one of the most important tools for improving the quality and affordability of health care for the American people. Imagine a future when families finally know which hospitals, doctors, and other elements of our health care system are at the cutting edge of providing high quality, cost-effective care; when employers can make data-driven decisions about which prescriptions to include in their employee health benefit plans solely on the basis of evidence; and when public health officials and clinical researchers can identify approaches to health and therapies that are demonstrably effective and efficient.

And yet, despite vast advancements in technology and the use of data across almost every aspect of the lives of Americans, health care data largely has remained disconnected, siloed, and out of reach for many providers, public policy makers, researchers, and consumers who seek to understand the problems in the U.S. health care system and to devise solutions to those problems. As a result, the health care sector lags behind most other industries in the ability to leverage data to improve timely delivery of the most appropriate services at affordable costs to patients and others who pay for health care. As highlighted by other provisions of the *No Surprises Act*, the health care sector is struggling with making the most basic information available. Important items such as the cost of a health care service, whether a provider is within an insurance network, or the amount of cost sharing required from consumers remain elusive.

Commercial health care claims data have mostly remained unavailable and inaccessible to some stakeholders who could use these data to improve the quality of health care, identify which hospitals and providers are high quality, help eliminate waste and inefficiency, and drive much needed innovation in our nation's health care delivery and payment system. In the last 20 years there have been efforts to make more effective use of health care data. However, progress has been slow.

HEALTH PLANS AND THE ROLE OF THE DEPARTMENT OF LABOR

¹ [U.S. Health Care from a Global Perspective, 2019 | Commonwealth Fund.](#)

² KFF, [2020 Employer Health Benefits Survey](#), published Oct. 8, 2020.

The U.S. has a patchwork of health insurance coverage, with individuals obtaining health care coverage through various mechanisms, including: employer-sponsored health plans, individual plans purchased directly from health insurance companies or through a health care marketplace, the Medicare program for those over 65 and younger people with disabilities, and Medicaid for those who qualify for subsidized insurance coverage. However, a significant majority of people with nonpublic coverage (approximately 165 million people) get their health insurance through an employer. Some employers and employer groups, often referred to as purchasers, offer fully insured group health insurance plans by purchasing a health insurance policy. The health insurance policies are sold by health insurance companies, which are largely licensed and regulated at the state level, in conjunction with Federal law such as the Affordable Care Act.³ But many large employers, including labor trusts and public entities, opt to provide health benefits through a self-funded arrangement where the plan or plan sponsor assumes the risk of paying claims. This type of arrangement often involves contracting with a third-party administrator (TPA) to process the claims. Not all self-funded plans are regulated by ERISA. For example, state and other governmental employee health plans are not covered by ERISA.

ERISA is the Federal law that sets minimum standards for most voluntarily established employee benefit plans by private sponsors to provide protection for individuals in these plans. Central goals of ERISA are the provision of stable and reliable benefits to employees, and the creation of uniformity and ease of benefit administration, particularly for employers or employee organizations operating in multiple states. For this reason, ERISA generally preempts state law. In 2016, the U.S. Supreme Court held, in *Gobeille v. Liberty Mutual Insurance Co.*,⁴ that ERISA pre-empts state laws that would require submission of data by ERISA plans to State APCDs.

Oversight of the most common form of private health insurance in our nation ultimately remains with the Federal government -- all guidance and requirements for the collection of the most common form of private health care claims data -- "self-insured data" -- is overseen almost exclusively by the Department of Labor. Passage of the *No Surprises Act* at the end of 2020 and the subsequent focus of Congress on providing assistance to States in collecting health care claims and encounter data presents a very important moment for the DOL and Secretary Walsh. The Department can advance policies that enable the development of comprehensive State APCDs by working to include data from self-funded group health plans to fully reflect the claims experience of self-insured populations. It is critical that DOL recognizes the role that the secure aggregation and analysis of self-insured health plan cost and utilization data, combined with data from fully-insured plans and other payers, can play in building a comprehensive understanding of the health care system in those states that have an APCD. Thus, DOL's facilitation and

³ The Patient Protection and Affordable Care Act, Public Law 111-148, was enacted on March 23, 2010, and the Health Care and Education Reconciliation Act, Public Law 111-152, was enacted on March 30, 2010. (These statutes are collectively known as the "Affordable Care Act".)

⁴ 577 U.S. 312 (2016).

support of the secure aggregation and use of these data and reporting by states are key aspects of DOL’s legal responsibility to oversee the administration of ERISA-covered health benefit plans.

EMPLOYER FRUSTRATION WITH COST OF HEALTH CARE

Overall, large employers find health care costs excessive and that the health care spending burden “will become unsustainable at some point in the next five to ten years,” according to a recent Kaiser Family Foundation (KFF) survey.⁵ The survey also notes that:

While annual growth in benefit costs has been modest in recent years (at least relative to prior decades), benefit costs are already high and they continue to increase faster than wages and prices in general. Employer health plans already pay much higher prices for health care goods and services than public coverage programs, and the gap is growing

Employers also struggle with the increasing complexity associated with annual assessments of how to deliver reasonably comprehensive benefits to employees that represent a good value for employees and the business. In this process they are working with a host of consultants and intermediaries just to manage the complexity, without necessarily having the data to evaluate overall performance.

RISING COST OF HEALTH CARE AND VARIATION IN QUALITY IMPACT EMPLOYEES

When health care costs rise, employers can respond in a variety of ways, such as by shifting costs to workers through increased premium contributions, deductibles, and copayments; reducing benefits; reducing employment; and/or increasing the employer’s premium contributions, which could limit wage growth. Research done in 2005 found evidence of wage rigidity and its impact on workers during a period of rapid premium growth.⁶

Use of State APCD data has helped to shed light on the cost of health care at the local level with price transparency tools, helping to drive down the cost of care, as was detailed in a 2019 study by Zach Brown.⁷

State APCD data have also been used to report variation in cost and health care quality, as well as wasteful health care spending that is not supported by evidence-based guidelines.⁸ For all of the above reasons, State APCD reporting is in the best interest of participants in employer-provided health plans.

⁵ KFF, [2020 Employer Health Benefits Survey](#), Oct. 8, 2020.

⁶ Sommers, Benjamin D., [Who Really Pays for Health Insurance? The Incidence of Employer-Provided Health Insurance with Sticky Nominal Wages](#), International J. of Health Care Finance and Economics, March 2005.

⁷ Brown, Zach Y., [Equilibrium Effects of Health Care Price Information](#), Oct. 1, 2019.

⁸ National Conference of State Legislatures, [Collecting Health Data: All-Payer Claims Databases](#), Apr. 1, 2018.

BACKGROUND INFORMATION ON STATE APCDS

State APCDs collect claims and enrollment data from multiple public and private payers that include transaction details such as the amount charged and actually paid for health care services and procedures, as well as detailed coding data related to diagnosis and type of treatment received.⁹ The first State APCDs were established in the early 2000s. For over a decade, states that had established APCDs required health plans to submit data to APCDs for all plans that they administered, whether fully insured or self-funded.

According to a history of APCDs:

State APCDs were originally developed to provide a single source for claims and enrollment data across all (or most) sources of insurance coverage within a single state. As their name suggests, multiple payers (health insurers) submit data on claims and enrollment. By including data from public programs (such as Medicare and Medicaid) and private insurers (including both employer-sponsored insurance(ESI) and other non-group insurance), APCDs as originally conceived have the potential to allow the study of utilization, spending, prices, and enrollment across payers accounting for the vast majority of health care spending in the states they cover.¹⁰

State APCDs also represent an opportunity for addressing public and population health challenges by helping policy-makers, researchers, and others to understand trends in chronic disease, study rare diseases, and assess the effectiveness of alternative treatments and therapies. However these opportunities can be addressed only in states that have functioning APCDs. Currently, only 18 states have fully functioning APCDs. In addition, 7 states have APCDs that are in the planning and development stage. Other data aggregation organizations, such as the Health Care Cost Institute, can provide similar insights at the national, and in some instances, the state level but do not receive data from all payers or insurance companies.

APCD creation expanded to include many states during the first two decades of the 2000s due to the lessons learned from early APCD adopters such as Maine, New Hampshire, and Maryland. State APCDs are used to provide a variety of information to policy makers, the public, and various other stakeholders.¹¹ Examples of such information include health care prices and other forms of transparency, utilization and quality, public health matters, evidence of inefficiency and waste, and outcomes of health reform.

⁹ APCD Council, [Interactive State Report Map](#) (2021).

¹⁰ Carman, Dworsky, Heins, Schwam, Shelton, Whaley, [The History, Promise and Challenges of State All Payer Claims Databases](#), Rand Health Care, June 2, 2021, citing Freedman, Green, and Landon, [All-Payer Claims Databases -- Uses and Expanded Prospects after Gobeille](#), New England Journal of Medicine, Vol. 375, No. 23 (2016).

¹¹ APCD Council, [APCD Showcase: States Leading by Example](#).

As more states have developed APCDs, some states have developed their own data layout and reporting requirements for data submitters (e.g., health plans), and some states may capture more expansive data sets as a result of their founding legislation or guiding policies. Health plans assert that state variations in submission requirements create a regulatory burden and are concerned that this burden will grow as more states adopt APCDs. The *No Surprises Act* authorized the Secretary of Labor to establish the SAPCDAC to provide guidance to the Secretary on establishing a standardized reporting format for states to collect ERISA self-funded plan data. The SAPCDAC's recommendations are based on existing APCD data layouts and operational experience, so that insurance carriers or TPAs, as applicable, can submit data in the same data feed on behalf of fully insured plans, self-funded ERISA plans, and self-funded plans not covered by ERISA.

In 2016, the U.S. Supreme Court held in *Gobeille v. Liberty Mutual* that states cannot compel self-insured plans regulated by ERISA to submit their data to State APCDs. Until this decision, data submission did not require a data submitter (typically a health insurance company, TPA or provider) to identify the plan type or whether a self-funded payer was regulated by ERISA; they simply submitted all commercial data to the State APCD. Following *Gobeille*, insurance companies and other data submitters had to unbundle their data submissions, create processes for identifying the ERISA self-funded plan data, and remove the data from files if an employer did not want the plan to submit data. However, at this point it is not clear to what extent employers are actively involved in the decision to have their data submitted to State APCDs. In any case, submission of commercial claims data, primarily as a result of the Supreme Court's decision, have fallen precipitously across states.

The resultant loss of a significant amount of ERISA self-funded plan data in APCDs has impacted the ability of State APCD data users to fully understand the health care marketplace and its population. In addition, data users have a reduced ability to study health equity, estimate the uninsured, determine total dollars spent on health care, assess the effectiveness of health care delivery to State residents, and analyze quality of care, patient safety, and care variation. This loss of data may impact evidence-driven policy making across states with APCDs.

Some states have already implemented a voluntary opt-in provision for ERISA-regulated health plans. When a plan sponsor notifies its service provider (such as a TPA) that it would like its data included in the submission, the group identifier of the plans that are included is added through simple modifications in submission algorithms. This step is not a separate reporting requirement for the insurance company and does not add to meaningful reporting burden.

THE HIPAA RULES AND APCDS

HIPAA privacy and security regulatory requirements (the HIPAA Privacy and Security Rules) do not apply to APCDs. As detailed in later parts of this Report, State law and administrative provisions for privacy and security govern State APCDs.¹²

Certain state agencies that administer an APCD may be HIPAA-covered entities¹³ because they administer health plans or are covered health care providers. If the agency performs some covered functions (i.e., those activities that make it a provider, a health plan, or a health care clearinghouse) and other non-covered functions, such as running an APCD, it may designate those components (or parts thereof) that perform covered functions as the health care component(s) of the organization and thereby become a type of covered entity known as a hybrid entity. Most of the requirements of the HIPAA rules apply only to the hybrid entity's health care component(s). If an agency is a hybrid entity, the health information held by the APCD it administers would not be covered by the HIPAA Rules.

Covered entities may disclose protected health information¹⁴ (commonly referred to as PHI) if the disclosure is within one of the Privacy Rule's listed permissions and follows its conditions. For example, depending on State law, a health plan may disclose PHI about its plan members to APCDs for public health, health system oversight (which includes longitudinal tracking of chronic care management and health outcomes), or because the disclosure is otherwise required by law. Once information has been disclosed to an entity that is not a HIPAA covered entity or business associate -- such as an APCD -- the information is no longer protected by HIPAA. APCD information is subject to varying state-level data privacy and security regulations. Independent of their status under HIPAA, many states have chosen to implement certain HIPAA Privacy and Security Rule provisions to ensure consistent management of claims data and PHI among stakeholders and data submitters.

¹² See, Attachment A, "Data Privacy and Security Resources Noted in Report," below.

¹³ See 45 CFR 164.103 and 45 CFR 164.105.

¹⁴ Protected health information is an individual's medical records and other individually identifiable health information maintained or transmitted by or on behalf of HIPAA covered entities.

RECOMMENDATIONS BY THE COMMITTEE

The Committee's recommendations provide guidance to Secretary Walsh and the Federal government in developing a standardized reporting format for the voluntary reporting by self-funded group health plans to State APCDs, as well as guidance on several key aspects about the process by which states may collect such data from self-funded plans. SAPCDAC has identified key operational elements for the collection of data from self-funded plans and has organized its recommendations to address four areas of focus: standardized data layout, process for data submission, privacy and security concerns, and a standardized process by which self-funded group health plans can voluntarily participate in data reporting.

STANDARDIZED DATA LAYOUT RECOMMENDATIONS

Background and Information

A standardized approach to data capture, exchange, and use is a cornerstone for coordinated, efficient processes and operations across numerous industries. Health information technology standards cover a wide spectrum of topics, including definitions and meanings for terms and codes used in health care, structures for data formats, and methods for security and data transport. These standards, developed and maintained by standards development organizations (SDOs),¹⁵ government agencies or other organizations, are used routinely in administrative, clinical, and business processes by all health care stakeholders.

Examples of health care codes and terminologies used routinely within the health care industry include, but are not limited to:

- Current Procedural Terminology (CPT® Codes) maintained by the American Medical Association, and related derivative code sets, such as the Healthcare Common Procedure Coding System (HCPCS);
- Code on Dental Procedures and Nomenclature (CDT Codes) maintained by the American Dental Association;

¹⁵ A standards development organization (SDO) is an organization whose primary function is to create uniformity in data specifications, terminology, protocols, etc., through consensus-based processes inclusive of all relevant parties (for example, consumers, government agencies, producers, etc.), and more. The American National Standards Institute (ANSI) is the accrediting body for SDOs ensuring the integrity of standards setting processes by accrediting SDOs based on factors such as balance of represented interests, openness, and consensus decision-making, among others. In cases where standards development work is run through a reputable professional society or industry group, they may not be ANSI accredited, but will, however, follow similar processes to ensure the integrity of their standards setting process. Examples of SDOs include ASC X12, HL7, NCPDP, NUBC, NUCC, NAIC, and IHE.

- International Classification of Diseases (ICD-10 Codes) maintained by the World Health Organization;
- Diagnostic and Statistical Manual of Mental Disorders (DSM-5) maintained by the American Psychiatric Association; and
- National Drug Code (NDC) maintained by the U.S. Food and Drug Administration.

Examples of standards used for the electronic format and exchange of health data and related information include, but are not limited to:

- Accredited Standards Committee X12 -- standards used commonly for processing and billing of medical claims; and
- National Council for Prescription Drug Programs (NCPDP) -- standards used commonly for prescription routing, and the processing and billing of pharmacy claims.

Because no single standard covers all possible health care applications, stakeholders use a variety of standards and corresponding implementation guides to define a robust and interoperable process for data capture and exchange. There is a significant opportunity to achieve greater efficiency and reduce burden and cost for all parties through greater standardization of data definitions and processes for submitting claims data to third parties.

During the course of the Committee's work, experts and affected stakeholders discussed emerging standards for health care transactions, such as the Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR) specification used by electronic health record (EHR) vendors, health IT developers, and a growing number of payers for clinical and some administrative data exchange.

While considering a uniform data layout for APCD reporting, the Committee identified several key factors that a standard data layout would need to have for use by APCDs and their submitters. A uniform data layout should:

- Reference known established open industry standards such as those developed by standards development organizations serving similar functions of standards stewardship, when possible;
- Reference mature standards that are in widespread use and have been tested for their specific uses, when possible; and
- Reference standards that are technically feasible for APCDs and submitters to adopt and use in the short-term without undue burden.

To this end, the Committee has identified the APCD Common Data Layout (APCD-CDL or CDL) as an immediately available starting point for a uniform data layout for adoption by APCDs and submitters. The APCD-CDL, developed by the APCD Council, as described in the next paragraph, is free and available for widespread use by the DOL.

Anticipating a need for a uniform data layout, in 2016 the APCD Council, a partnership of the National Association of Health Data Organizations (NAHDO) and the Institute for Health Policy and Practice at the University of New Hampshire, convened State APCD representatives, vendors, and interested stakeholders that included many regional and national health insurance plan representatives. The goal was to develop a single data layout that reflected the data elements needed by various states for APCDs and provided consistency for the data elements that are common across states (which are most of the data elements). The APCD-CDL was developed by reviewing and reconciling all existing APCD data layouts with State APCD representatives, vendors who provide data collection services to APCDs, and health plans to create a uniform common layout (e.g., the same data elements in the same positions, with the same naming structure, and same references) that would satisfy most of the needs of State APCD organizations. The APCD-CDL working group worked through each data element, eliminating fields, clarifying definitions and expectations, and incorporating references to standards, including X12 and NCPDP, where appropriate.

It is important that the uniform data layout for voluntary submission of data by self-funded health plans is the same as the data layout used for collection of APCD data from all plan types to reduce the burden on service providers (such as health insurance companies or TPAs) used by employers with self-funded plans, whenever possible. Significant investment has been made by States and the Federal government to develop existing APCDs. Adopting the APCD-CDL as a uniform standard for self-funded plans will mirror the existing State APCD layouts and will further support the work being done by States.

As is the case with fully insured data and self-funded data currently being submitted to State APCDs, some self-funded data collected through a process recommended by DOL may not be part of claims collection. Uniform data collection for submission to State APCDs for all data types would allow carriers to standardize content and timing of data delivery for all states.

RECOMMENDATIONS FOR STANDARDIZED DATA LAYOUT

- **Recommendation 1:** In the immediate term, the DOL should use the content of the APCD-CDL as the basis for the standard reporting format for submitting self-funded plan data to APCDs. The APCD-CDL is a good starting place for states as it provides a standard set of data elements that can be readily used today. Additional considerations include:
 - Adoption of the data layout detailed in the APCD-CDL should be done in full, the data elements should be ordered consistently, and if a state is unable to capture a data element (for example, due to a state law prohibition), an empty field may be allowed.

- State APCDs need to capture care and cost at the local level and there may be a need for the collection of data elements to capture differences across states in health markets and plan types. If there are additional state-specific data elements not specified in the APCD-CDL, the additional elements, if requested of a payer by a State APCD, should be appended to the end of the APCD-CDL or as a separate file. If additional data elements are common to multiple states, they should be added to the CDL in the future in satisfying the Secretary's obligation under ERISA section 735 to periodically update the standardized reporting format. This process is noted in Recommendations 2 and 3.
- States that currently have a different data submission format may need a transition period to adopt the new APCD-CDL format, including time for rulemaking. The DOL should work with State APCDs to understand the implementation processes and timelines for transitioning to the CDL.
- **Recommendation 2:** There is recognition that the APCD-CDL does not include data elements that capture non-claims payments made to health care providers. Given the importance of including these payments in understanding total health care spending, the DOL should work collaboratively with states to capture non-claims payments and other important variables needed to support cost and utilization analyses.
 - The APCD-CDL, if recommended by the DOL as the standard reporting format, should be enhanced to include other important variables needed to capture the totality of payments to providers. These non-fee-for service payments include alternative payment models such as capitated payments, advanced primary care payments, bundled payments, and performance-based incentives. The APCD-CDL should also capture other variables needed to enable cost and utilization analyses, including plan benefit design and cost-sharing features, and the actuarial value of plans.
 - Because data standards do not currently exist to represent these other desired data elements, the DOL should work with stakeholders to determine what additional high priority data elements should be contained in data submissions to APCDs and create standards and a process for submitting such data. Health plans could submit data on non-claims-based payments in a separate file from the APCD-CDL.

- **Recommendation 3:** A detailed data dictionary¹⁶ should be created for the elements included in the APCD-CDL data layout. The data layout will evolve over time in response to changes in health care markets and innovations in payment policies. Accordingly, the standard data layout will require updating.
 - The DOL should identify an ongoing stewarding body¹⁷ to maintain and update the uniform data layout detailed in the APCD-CDL. Entities for consideration should be multi-stakeholder organizations capable of reconciling both content and technical requirements for implementers. Standards development organizations have existing processes in place, and some of the elements in APCDs are maintained by those SDOs. DOL should explore how to leverage the existing functionality for updating and maintenance of the format, including the APCD-CDL Maintenance Process included in the Appendix.

DATA SUBMISSION RECOMMENDATIONS

Background and Information

States with existing APCDs have been capturing the data for a number of years. The most common approach involves the exchange of flat text files¹⁸ containing retrospective data, sent via Secure File Transfer Protocol (SFTP),¹⁹ with quality checks for data completion and validation of data submission, and with communication to data submitters about file errors (to work through data quality concerns). New York is the only state not using flat text files.

There are some modest variations in current state practices concerning the data submission process that can pose a challenge in uniformity. There also is variation in the frequency of submission: some states require data submission on a monthly basis; some are quarterly, and some are yearly. There may be significant challenges for states and data submitters in adopting uniform processes if the DOL recommends a method of reporting for voluntary self-funded plans that varies from current state processes or laws. States may need time and resources to adapt existing processes to address these issues. They may need to coordinate changes in partnership with data submitters, identify funding to support the changes that data collection vendors need to adopt, and be required to go through a formal, multi-year rulemaking process.

¹⁶ A data dictionary is a document that provides clear definitions of each named data element, and includes specific attributes for each data element. It provides a consistent representation for each data element on how users should code, format, and interpret data and/or their corresponding data fields.

¹⁷ An ongoing stewarding body is an organization that will provide management and oversight of data layout to help provide users with high-quality content that is accessible in a consistent manner and updated at regular intervals or when deemed necessary.

¹⁸ A flat file is a text file where each line holds one record, with fields separated by delimiters, such as commas, pipes, or tabs. A CSV file is an example of a flat file.

¹⁹ A Secure File Transfer Protocol is a network protocol for accessing, transferring, and managing files on remote systems.

New methods of data exchange and quality control standards may be developed in the future that could improve the speed, quality, and efficiency of data submission and data receipt. Several SDOs are addressing health information transmission methods that may provide efficiencies for future exchange of claims data, including maintaining APCDs. There should be continued attention (through some sort of formal mechanism or designated group) to evaluate newer technologies that would advance State ACPD data acquisition and support state adoption when proven.

RECOMMENDATIONS FOR DATA SUBMISSION

- **Recommendation 4:** In the immediate term, existing state methods for APCD data collection should be encouraged or a process for data submission should be implemented that mirrors the existing common state methods for APCD data collection.
 - States should maintain current data submission and receipt processes with an eye for any necessary or future changes as new methods for data collection emerge.
 - States newly developing an APCD should adopt a data collection process that is most efficient for both the state and their data submitters, while recognizing that the goal is to have as much commonality across states as possible.
- **Recommendation 5:** DOL, in consultation with APCD stakeholders, should identify an ongoing process whereby states can periodically evaluate current, alternative, and emerging standards for data submission, and methods for quality assurance.
 - The Committee heard from experts about emerging methods for data sharing that work well in some situations but members of the Committee shared concerns that these methods would not meet the data quality assurance needs of State APCDs.
 - New technology and methods for sharing data will continue to evolve. A unified process for identifying alternatives to the current process that meets the needs of State APCDs will benefit data submitters as well as State APCDs.
- **Recommendation 6:** States should, to the extent possible, collect data on a uniform monthly timeline.
 - A uniform timeline along with a standardized data layout will provide a simpler process for those that submit data to State APCDs.
 - In most states, data submission by health plans occurs on a monthly basis, which allows for data to be collected and checked on a regular basis. Data submission on a

monthly basis also limits to a short-time period resubmission of data to correct bad files when a data submitter recognizes an error. Aligning to this frequency would cause the least disruption to current processes at the health plan and state levels. However, alternative payment methods, such as capitated payments, could be submitted on an annual basis.

- States currently collecting files for alternative payment models and other non-claims based payments are doing so on an annual basis that is separate from the monthly data files received for all other APCD data.

DATA PRIVACY, SECURITY, AND RELEASE

Background and Information

Health plans have communicated their hesitancy to release plan members' claims data to APCDs out of concern for the privacy and security protections that would apply to that data. This section aims to clarify the protections provided by APCDs and includes recommendations for creating uniformity among states for privacy, security, and release of APCD data to address the questions that some have raised.

HIPAA privacy and security requirements apply to “covered entities,” which are health care providers that use certain electronic transactions related to payment, health plans (including employer-sponsored plans and Federal programs), and health care clearinghouses, as well as the business associates of covered entities.²⁰

Covered entities must safeguard protected health information they are sharing with an APCD (including applying appropriate safeguards during transmission). Once the data are received by the State APCD, the covered entities are no longer responsible for protection of the data.

State APCDs have implemented data security protocols and data release procedures; the Committee heard testimony from State APCDs as well as other experts, including NAHDO, that are familiar with the relevant state laws and procedures. Data security is a priority for states. In establishing APCDs, many states voluntarily implement provisions of or use the HIPAA Privacy and Security Rules to inform their practices regarding data privacy and security and data release. Additionally, many APCDs are subject to state regulations that mirror HIPAA privacy and security regulatory requirements.²¹

²⁰ See Attachment A and <https://www.hhs.gov/hipaa/index.html> for information about the HIPAA Rules.

²¹ See APCD Council, [APCD Legislation by State](#) (2021).

Data release rules need to strike a balance between information privacy protection and ensuring access to the data needed to address critical policy problems, including health care costs and drivers of spending, the impact of market consolidation, disparities in care, and quality of care.

State APCDs each have customized data use agreements (DUAs) and data release processes. However, many states have indicated an interest in the creation of a standard data use agreement and process, possibly similar to the Healthcare Cost and Utilization Project (HCUP) process, maintained by the Agency for Healthcare Research and Quality (AHRQ). A possible Federal role would be to negotiate with State APCDs to implement uniform agreements and processes. This would allow greater utility of the data for research across states. It would also relieve states from independently developing local standards “from the ground up.”

State laws that address permissible uses of the data vary, which can limit release and utility of data, particularly for multi-state research.

Expert testimony by Norman Thurston and Charles Hawley, representatives from the NAHDO, illustrated the commonalities among State APCDs in implementation of specific data protection activities and considerations for data release. These commonalities are important components of any comprehensive state data privacy protection program. Additional safeguards may need to be considered to ensure that critical data elements are available to address important issues. While the Committee does not recommend a singular privacy and security framework, states can draw on several models and resources included in the appendix from the National Center for Health Statistics (NCHS) and the National Institute for Standards and Technology (NIST).

RECOMMENDATIONS FOR DATA PRIVACY AND SECURITY

- **Recommendation 7:** Existing State APCDs should maintain, and new State APCDs should develop and implement, rigorous privacy and security protections for the health information they receive, maintain, and release, including comprehensive administrative, technical, and physical safeguards. The focus of these protections is to ensure that the identity of individual patients are secured. These steps protect the privacy of state residents and respond to certain concerns of data submitters that want assurances that the data are secure when held at a State APCD.

Some key issues that should be addressed include, but are not limited to:

- De-identification methodologies to create public use data sets and the use of longitudinal identifiers;
- Data use agreements;
- Review process for applications to use the data;

- Security and privacy protocols for data release (such as through a data enclave, data in transit, and data that are received and held by data users);
 - Authorized users and uses of the data;
 - Disposal of the data once the period of use is completed;
 - Attribution and acknowledgment of the use of the data; and
 - Penalties for violations.
- While the Committee recognizes that some State APCDs collect individually identifiable data to enable data linkage to other data to examine health outcomes and social determinants of health, the reporting of information using these data should focus on the health system as a whole, on aggregated data findings and public health issues and never in a way that would allow for constructive re-identification of the individuals. Public data release should never be conducted in a way that may allow identification of an individual patient. State APCDs should determine the conditions under which identifiable data may be combined with other data sets to enhance their utility (for example, conditions for augmenting socio/demographic or other population characteristics).
 - The DOL should consider the utility and feasibility of developing and implementing a uniform set of data release protocols/requirements and DUAs for State APCDs to protect the data and allow potential users to access the data with appropriate privacy and security safeguards.

This overall recommendation supports the principle that protection of the privacy and security of health information supports State APCDs in providing data to address public health issues and to improve health care and health care delivery in the U.S. An important element is the timely release of data to approved data users while protecting privacy. The Committee recognizes that individual state laws may dictate how State APCDs collect and release data.

- **Recommendation 8:** Where permissible under state laws,²² APCDs should develop an infrastructure and implement a process that is adequately resourced to ensure timely release of data to approved data requesters. This process should be well-articulated, transparent, and include all steps involved, such as:
 - Information that must be supplied in the application;
 - Receipt of application;
 - Review of applications;
 - Required modifications (if any) of the application to permit use and transmission of data to approved users; and

²² Some states, such as Minnesota, do not permit the release of APCD data.

- Transmission of data to approved users.
- **Recommendation 9:** While individual State APCDs have their own data dissemination processes, states should explore establishing a secure, privacy-protective, multi-state data aggregation and dissemination model that would permit wider use of the data. Several [public](#) and [private](#) sector models exist which may serve as a framework for sharing data sets in this way. For example, a single entity may be responsible for disseminating a data file that contains a select number of APCD data elements under a standard DUA (recommended above) acceptable to a large number of State APCDs that would support multistate research. Consideration should be given to how these activities may be funded and supported, including Federal involvement, and to whether such changes to data release practices will require amendment of state laws to align with this concept.

VOLUNTARY DATA SUBMISSION

Background and Information

The Committee considered how states can have a uniform process for collecting data from self-funded health plans with the goal to simplify and harmonize the data submission process to allow for ease of submission for group health plans operating in various states. Many employers, other sponsors of self-funded plans, and the public are not aware of the critical role that health care claims data -- including self-insured data from group health plans -- play in effectively overseeing the health and well-being of our nation. Sponsors of self-insured plans also may not be aware of how important these data are and the importance of participating in State APCDs.

As mentioned above, in *Gobeille vs. Liberty Mutual*, the U.S. Supreme Court ruled that states could not require self-funded group health plans to submit claims data to APCDs. As a result, State APCDs have lost access to data for many individuals in group health plans. This has limited the generalizability of data contained in State APCDs and removed the health care experience of millions of Americans from the critical work done by State APCDs.

Experts discussed some of the public policy benefits of comprehensive State APCDs for all stakeholders across the health care system, which include the ability to analyze the impact of provider consolidation or identify the highest cost providers. The experts also spoke about benefits to employers of submitting data, such as the ability to compare their plan to other plans or to inform plan benefit design.

On the other hand, experts also addressed some of the disincentives for group health plan participation in State APCD data submission, which include state variation in opt-in processes and concerns that the employers would be required to pay for data submission activities undertaken by TPAs. Experts also mentioned the incomplete understanding among employers about the existence and value of State APCDs. In addition, employers' reliance on TPAs for their health benefit plan management and administration places an entity that may have an economic

or business interest in *not* submitting data in an advocacy or decision-making role about State APCD data submission.

In some instances, either real or perceived obstacles exist that create challenges for self-insured plan sponsors to submit data to State APCDs. For example, there can be considerable variation across states on how a plan sponsor may opt into providing data. In addition, TPAs may not follow through on a plan sponsor's decision to submit data or may establish other obstacles such as charging fees or raising unfounded legal concerns.²³ There was deliberation within the Committee about the feasibility of an opt-out model for employers to submit data to State APCDs that would require a health plan to actively choose not to participate in APCD data submission, otherwise the data would be included. While there is general agreement among Committee members that this would likely result in more data being submitted to State APCDs, there are concerns that such a process would not withstand legal challenges.

RECOMMENDATIONS FOR VOLUNTARY DATA SUBMISSION

- **Recommendation 10:** The Secretary of Labor, in partnership with the Secretary of HHS, should clarify and emphasize the public policy and business interests of having self-funded group health plans submit data to State APCDs. This could be done through annual communication to self-funded plans or as a public policy statement, whichever would be most effective.

These benefits include, but are not limited to:

- Improving the quality and affordability of health care services;
- Providing consumers with information on quality of care, outcomes of care, and costs of treatment;
- Identifying and ameliorating health inequities within and across specific socioeconomic and demographic groups (such as people of color, rural residents, and children);
- Oversight and regulation of the health care sector;
- Understanding the impact of proposed regulatory and legislative changes; and
- Other public health uses.

The Secretaries of Labor and HHS should consider convening a roundtable of self-funded employers or publishing a white paper to:

- Highlight and document the benefits of State APCDs; and
- Shed light on commercial data entities that were not impacted by the *Gobeille* decision that are currently receiving self-funded plans' data, how it is being used, and how the same data could be used by State APCDs.

²³ Fiedler, Matthew and Linke Young, Christen, [Federal Policy Options to Realize the Potential of APCDs](#) (USC-Brookings Schaeffer Initiative for Health Policy: October 2020), p.7.

- **Recommendation 11:** DOL should make it easy for self-insured group health plans to participate in APCD data submission by establishing an effective and streamlined process for self-insured group health plans to opt in for data submission by creating a standard opt-in process.
 - Initially, create a standard process with Federal support that allows self-funded group health plans to opt in at the state level using a standardized online portal or standalone standard APCD opt-in form that could be shared and used by states that includes information on State APCDs and asks health plans to respond to questions.
 - The standard process should include defined use cases,²⁴ including those created in Recommendation 10, and specifications for adoption of standard data privacy and security, CDL adherence, and other matters consistent with the recommendations adopted.
 - States that do not adopt the standardized process would continue to seek participation using existing methods. States developing a new APCD should be urged to use the new standard process.
 - To further encourage participation, create a Federal process managed by DOL (such as allowing self-insured group health plans to opt-in via the DOL annual [Form 5500](#) or another option identified by DOL) that includes specific language on the benefits of plans opting in. This type of process would require DOL to collect responses and communicate them to both states and TPAs to make sure all parties are informed.
 - Clarify that the decision to submit data rests with the self-insured group health plan, not the TPA, by recommending model contract language for group health plans to use to authorize APCD data submission.

²⁴ The term “use case” in the context of State APCDs refers to a concrete example or description of how end-users will use the APCD or information from its database to achieve their goals and objectives. A use case is often very specific to particular audiences, such as researchers, public, and private decision-makers/policymakers, consumers/patients, employers, payers, healthcare providers, and health plans. For example, a use case for researchers may be different from a use case for a patient. Researchers may be interested in using a particular State APCD to conduct sophisticated analyses to address a particular policy issue. Patients may be interested in reports or tools created from the use of an APCD to inform their healthcare decisions. Health care providers may use aggregated statistics from State APCDs to benchmark their performance. In general, a use case is aligned to a specific audience, product (such as a database, report, or tool), and purpose. A use case demonstrates the value or potential value of State APCD.

- Survey group health plans annually and report publicly about any difficulty group health plans are experiencing in submitting data, and in particular, working with TPAs. This should also include reasons why group health plans may choose not to submit data. The Secretary should provide guidance to group health plans and State APCDs about common difficulties reported (for example, legal concerns and unreasonable fees).

ADDITIONAL RECOMMENDATIONS

- **Recommendation 12:** DOL should engage employers and unions that sponsor self-insured ERISA-covered group health plans to assess what, if any, changes to data submission processes could increase and enhance self-funded plan participation in APCDs.
 - Even in states where there is an opt-in process for self-funded plans currently in place, many self-insured plans do not submit data. The Committee heard from stakeholders who noted numerous barriers to participation, including high TPA fees, even though the process for participation is not burdensome or complex.
- **Recommendation 13:** The Committee's work provides the Secretary of Labor with sufficient detail on a standardized layout and a process to collect self-funded plan data by State APCDs to provide guidance to states. This Committee recognizes the breadth and complexity of the issues related to APCDs and recommends that there be a committee or round table focused on State APCDs to work to fully address the issues beyond the scope of this Committee's charge (possibly with the current members, if they are willing to serve). This Committee would need to be adequately supported by DOL staff, as permitted by law, to perform its duties in an efficient manner.
 - DOL can learn a lot from states, and states can learn a lot from each other, to achieve even greater use of APCD and increased cooperation from data submitters with greater uniformity in approach to key areas not addressed specifically in this Report. States could achieve greater uniformity in data collection with the adoption of the APCD-CDL.
 - DOL should work collaboratively with states with APCDs to identify other aspects of data collection that could be streamlined for greater efficiency.
 - DOL should survey existing State APCDs data privacy and security protocols, synthesize these approaches, and identify common features or best practices beyond those identified in this Report.

- DOL should consider progress made over the time period for self-funded plans opting in to data submission and make recommendations to the Secretary of Labor for additional steps that he should take if targets for participation are not achieved, as noted in the section, Issues for Future Consideration, below in this Report.
- **Recommendation 14:** Despite broad interest in addressing pervasive health inequities across race, ethnicity, and gender, these data elements typically are not being collected by payers and, as a result, are not submitted rigorously to the states. The Secretaries of Labor and HHS should work with the states and stakeholders to make system-wide investments to better standardize the collection of these data.
 - Often these data are not consistently captured by health plans, not collected and/or not reported. Although State APCDs and the APCD-CDL include these data elements, they are often left blank. The Secretaries of Labor and HHS should work with the states, plan sponsors, health plans, and other stakeholders to encourage the collection and submission of these data. This would improve the ability to measure health equity and develop policies to address inequities.

ISSUES FOR FUTURE CONSIDERATION

DATA AND PRIVACY SECURITY CONSIDERATIONS

The Committee recognizes that the recommendations for data and privacy security are broad. More analysis would be required to enable the Committee to make more specific recommendations. Some examples of topics include the following:

- The Committee discussed how State APCDs have developed and implemented privacy and security protections of the data, both when maintained by the APCD and when released. The Committee also recognizes that clear and concise information on data privacy and security protections and potential uniformity of approaches are important factors in increasing participation of self-funded employers. The Committee suggests that the Secretary collect information on which practices are currently in place within State APCDs and evaluate the potential for further refinement or standardization. As part of its assessment, the Secretary should address what safeguards may be considered best practices, evaluate limits on uses and disclosures of data, use of encryption of data in transit and at rest, system access, system audits, and other security measures. The Secretary should make the findings publicly available.

VOLUNTARY DATA SUBMISSION CONSIDERATIONS

The Committee was created to advise the Secretary of Labor regarding a standardized reporting format for the voluntary reporting by group health plans to State APCDs. Throughout the Committee's deliberations, however, there was considerable concern that efforts to comprehensively secure voluntary submission of claims data to State APCDs might be unsuccessful within the framework established by the *No Surprises Act*. To date, and particularly after *Gobeille*, submission of data to State APCDs has declined, particularly among self-funded plans. One trade association for self-insured employers told that Committee that they prefer one central database because that is the most simple and least-burdensome approach to date submission (an important goal of DOL's oversight of ERISA benefits). Stakeholders expressed concern to the Committee that TPAs may be hindering efforts to collect these data to transmit to State APCDs because many TPAs have a business interest in commodifying these data and selling analytic tools for use with the data,²⁵ and/or concerns that the data would be used to disclose proprietary provider information on contracted rates.²⁶

However, some of these data are now required to be publicly reported as part of the cost transparency requirements in the *No Surprises Act*. Finally, the Committee emphasizes the

²⁵ Also see, Fiedler, Matthew and Linke Young, Christen, [Federal Policy Options to Realize the Potential of APCDs](#) (USC-Brookings Schaeffer Initiative for Health Policy: October 2020), Executive Summary and p.7.

²⁶ *Id.* p.6, citing in fn. 24 [Achieving States' Goals for All-Payer Claims Databases](#), Anthem Public Policy Institute, June 2018; Chamber of Commerce of the United States of America, [Letter to Senators Alexander and Murray regarding the Lower Health Care Costs Act](#), June 17, 2019,

substantial logistical and political difficulty of developing a comprehensive State APCD in each state, the District of Columbia, and the U.S. territories.

Given the tremendous public policy rationale for more effective collection and analyses of these data, the Committee is providing policy makers with the following longer-term recommendations:

- The Secretary of Labor should establish a date (the Committee recommends within three years) and a metric (for example, a target of data submitted for 80 percent or more of insured lives) by which DOL determines if voluntary data submission has succeeded to create more complete APCD data. If the target is not met, this could trigger one or many future actions, such as:
 - a) Administrative action or a recommendation for Congressional action to require uniform standards for submission and mandatory submission across group health plans, government sponsored insurance, and fully insured plans; including exploring what would be required to change the process to enable plan sponsors to opt out rather than opt in.
 - b) Action by DOL in its oversight role to centrally collect all claims data from self-insured employers that would be disseminated to states based on beneficiary geography (residence and utilization of health care services); while states continue to collect all other data. This could be through the creation of a small number of federally coordinated, regional APCDs; or a national APCD.
 - c) The Secretaries of Labor and HHS, to support states in the collection of high-quality, complete data, should monitor progress in securing data from government-sponsored coverage -- particularly, Federal Employee Health Benefits Plan (FEHBP), Veterans Administration (VA), Medicare Part D, and Medicare Advantage, as well as state sources of coverage including Medicaid and the Children's Health Insurance Program. If states surveyed about employer participation are not receiving data from these Federal programs, the Secretaries could communicate their support of data submission to State APCDs to their counterparts responsible for these data even though these agencies and data submitters are not under the authority of either Secretary.

List of Attachments

Appendix

Attachment A: Data Privacy and Security Resources Noted in Report

Attachment B: Acknowledgements

APPENDIX

APCD Council, NH Institute for Health Policy and Practice, and NADHO, APCD-CDL™

APCD Common Layout (Maintained by APCD Council Version 2.1| Released July 1, 2021



Embedded

APCD Council, [APCD-CDL™ Maintenance Process,” Common Data Layout](#) (©2009 - 2021 APCD Council, NAHDO, UNH).

Katherine Grace Carman, Michael Dworsky, Sara Heins, Dan Schwam, Shoshana Shelton, and Christopher Whaley, [The History, Promise, and Challenges of State All Payer Claims Databases](#) (RAND [Health Care Report](#), June 2, 2021).

National Center for Health Statistics of the Centers for Disease Control and Prevention, [Confidentiality and Security of Information Collected by The National Center for Health Statistics](#) (U.S. Department of Health & Human Services).

National Institute for Standards and Technology (NIST), [Information Technology, Privacy, Overview](#) (U.S. Department of Commerce).

OSHPD, California, [Office of Statewide Health Planning and Development, Health Care Payments Data Program: Report to the Legislature, March 9, 2020.](#)

ATTACHMENT A

Data Privacy and Security Resources Noted in Report

The [processes and documentation used by the National Center for Health Statistics \(NCHS\)](#) are relevant. NCHS uses confidentiality and data use agreements that can be used as models. NIST's [Cybersecurity Framework](#) provides a holistic organizational approach. The Framework includes implementation guidelines as well as measures for determining levels of implementation. [De-identification approaches](#) that may be relevant are described in [NIST's Guide to Protecting the Confidentiality of Personally Identifiable Information \(PII\)](#):

Several relevant approaches to health information stewardship exist and should be investigated for future considerations. The AHRQ HCUP, a Federal-State-Industry Partnership, has a central distributor mechanism for the dissemination of data for a wide number of independent organizations responsible for their data. <https://www.hcup-us.ahrq.gov/>. The processes and documentation used by National Center for Health Statistics (NCHS) are relevant, as are those used by the Centers for Medicare and Medicaid Services (CMS) and private sector organizations like the Health Care Cost Institute. NCHS uses confidentiality and data use agreements that can be used as models. <https://www.cdc.gov/rdc/index.htm>. Several states currently produce public use data files that are often designed with specific applications in mind and prevent the identification of a person or provider, and these could be used as a model. Similarly, the generation of synthetic data files from one or more APCDs could serve as tools to provide greater research access to more granular information.

Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104-191), and the HIPAA Rules

To improve the efficiency and effectiveness of the health care system, the [Health Insurance Portability and Accountability Act of 1996 \(HIPAA\)](#) requires HHS to adopt national standards for certain electronic health care transactions and security, as well as Federal privacy protections for individually identifiable health information.¹ The law identified three types of covered entities that are required to implement these privacy and security protections: health plans, health care clearinghouses, and health care providers who conduct any of the standard health care transactions electronically.² Congress has amended these requirements several times. HHS has promulgated the HIPAA Privacy, Security and Breach Notification Rules, collectively known as the HIPAA Rules. These Rules protect the privacy and security of individuals' medical records and other individually identifiable health information maintained or transmitted by or on behalf

¹ See <https://www.hhs.gov/hipaa/for-professionals/index.html>.

² See 45 CFR 160.102 and 160.103.

of HIPAA covered entities. This information is called protected health information, or PHI.³ As part of these protections, covered entities are required to have contracts or other arrangements (often called a business associate agreement) in place with business associates, who create, receive, maintain or transmit PHI on behalf of, or provide certain services involving PHI to, a covered entity or another business associate. Certain Privacy Rule requirements and all of the Security Rules' requirements apply to the business associates of covered entities.

The HIPAA [Privacy Rule](#) protects individuals' PHI by regulating how covered entities and their business associates may use and disclose PHI and by requiring covered entities to have policies and procedures and other administrative, physical and technical safeguards in place to protect the confidentiality of the information. The Privacy Rule also gives individuals rights with respect to their PHI, including the right to receive adequate notice of a covered entity's privacy practices, the right to request restrictions on use and disclosure of PHI, the right to access their PHI, the right to request an amendment to their PHI, and the right to receive an accounting of disclosures.⁴

The HIPAA [Security Rule](#) sets national standards for protecting the confidentiality, integrity, and availability of electronic PHI. The Security Rule requires covered entities and their business associates to implement certain administrative, physical, and technical safeguards to protect electronic PHI. Covered entities and business associates must perform ongoing risk analysis as part of their security management processes. The [Breach Notification Rule](#) requires covered entities to provide notification to affected individuals, the Secretary of HHS, and in some cases the media following a breach of unsecured PHI, and requires a covered entity's business associate that experiences a breach of unsecured PHI to notify the covered entity of the breach.

³ Subtitle F of title II of HIPAA (Pub. L. 104-191, 110 Stat. 1936 (August 21, 1996)) added a new part C to title XI of the Social Security Act, Pub. L. 74-271, 49 Stat. 620 (August 14, 1935), (see sections 1171–1179 of the Social Security Act, 42 U.S.C. 1320d–1320d–8)), as well as promulgating section 264 of HIPAA (codified at 42 U.S.C. 1320d-2 note), which authorizes the Secretary to promulgate regulations with respect to the privacy of individually identifiable health information. The Privacy Rule was amended pursuant to the Genetic Information Nondiscrimination Act (GINA), title I, section 105, Pub. L. 110-233, 122 Stat. 881 (May 21, 2008) and the Health Information Technology for Economic and Clinical Health (HITECH) Act, Pub. L. 111-5, 123 Stat. 226 (February 17, 2009). See also the HIPAA Security Rule, 45 CFR Parts 160 and 164, Subparts A and C, the HIPAA Breach Notification Rule, 45 CFR Part 164, Subpart D, and the HIPAA Enforcement Rule, 45 CFR Part 160, Subparts C, D, and E.

⁴ See 45 CFR 164.520, 164.522, 164.524, 164.526 and 164.528.

ATTACHMENT B

ACKNOWLEDGEMENTS

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