Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 2816 and section 206(18-a)(d) of the Public Health Law, Part 350 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is added, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

A new Part 350 is added to read as follows:

Part 350

All Payer Database (APD)

Sec.


350.1 Definitions

350.2 APD submission

350.3 APD data release

350.4 APD advisory group

350.5 APD guidance


§ 350.1 Definitions. For the purposes of this Part, these terms shall have the following meanings:

(a) "All Payer Database" or "APD" means the health care database maintained by the Department or its contractor that contains APD data.

(b) "APD data" means covered person data, claims data, and any other such data contained within standard transactions for Electronic Data Interchange (EDI) of health care data adopted by the Accredited Standards Committee (ASC) X12 standards

organization, the National Council for Prescription Drug Programs (NCPDP) standards organization, or any other organizations designated by the federal Department and Human Services to develop and maintain standard transactions for EDI of health care data, as provided in section 1320d-2 of Title 42 of the United States Code (USC) or any other federal law.

(c) "claims data" means:

(1) Benefits and coverage data – data specifying the benefits and coverage available to a covered person, such as cost-sharing provisions and coverage limitations and exceptions;

(2) Health care provider network data – data related to the health care provider and service networks associated with third-party health care payer plans and products, such as the services offered, panel size, licensing/certification, National Provider Identifier(s), demographics, locations, accessibility, office hours, languages spoken, and contact information;

(3) Post-adjudicated claims data – data related to health care claims that has been adjudicated by a third-party health care payer, such as the data included in the ASC X12 Post Adjudicated Claims Data Reporting and the NCPDP Post Adjudication Standard transactions; and

(4) Other health care payment data, such as value based payment information, as determined by the Department.

(d) “covered person” means a person covered under a third-party health care payer contract, agreement, or arrangement that is licensed to operate in New York State by the New York State Department of Financial Services.

(e) “covered person data” means data related to covered persons, such as demographics, member identifiers, coverage periods, policy numbers, plan identifiers, premium amounts, and selected primary care providers.

(f) “data user” means any individual or organization that the Department has granted access to APD data, with or without identifying data elements.

(g) “health care provider” means a provider of “medical and other health services” as defined in 42 USC § 1395x(s), a “provider of services” as defined in 42 USC § 1395x(u), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business. This includes a clinical laboratory, a pharmacy, an entity that is an integrated organization of health care providers, and an accountable care organization described in 42 USC § 1395jjj. The term also includes atypical providers that furnish nontraditional services that are indirectly health care-related, such as personal care, taxi, home and vehicle modifications, habilitation, and respite services.

(h) “identifying data elements” means those APD data elements that, if disclosed without restrictions on use or re-disclosure, would constitute an unwarranted invasion of personal privacy consistent with federal and state standards for de-identification of protected health information.

(i) “New York State agency” means any New York State department, board, bureau, division, commission, committee, public authority, public benefit corporation,

council, office, or other governmental entity performing a governmental or proprietary function for the State of New York.

(j) "submission specifications" means specifications determined by the Department for submitting covered person data and claims data to the APD, such as the data fields, circumstances, format, time, and method of reporting.

(k) "third-party health care payer" means an insurer, organization, or corporation licensed or certified pursuant to article thirty-two, forty-three, or forty-seven of the Insurance Law or article forty-four of the Public Health Law; or an entity, such as a pharmacy benefits manager, fiscal administrator, or administrative services provider that participates in the administration of a third-party health care payer system, including any health plan under 42 USC § 1320d. The term does not include self-insured health plans, although such plans that operate in New York State may choose to participate as a third-party health care payer.

§ 350.2 APD data submission.

(a) Third-party health care payers shall submit complete, accurate, and timely APD data to the Department, pursuant to the submission specifications.

(b) The Department shall consult with the Department of Financial Services and third-party health care payers before issuing any submission specifications.

(c) The Department shall set a compliance date of at least 90 days from the date that new or revised submission specifications are issued.

(d) Third-party health care payers shall submit APD data in an electronic, computer-readable format through a secure electronic network of the Department or its

designated administrator on a monthly basis, or more frequently, as specified in the submission specifications.

(e) Third-party health care payers shall submit at least 95 percent of APD data within 60 days from the end of the month of the adjudicated claims being submitted for payment.

(f) Third-party health care payers shall submit 100 percent of APD data within 180 days from the end of the month of the adjudicated claims being submitted for payment.

(g) The Department may audit APD data submitted by third-party health care payers to evaluate the quality, timeliness, and completeness of the data. The Department may issue an audit report or statement of deficiencies listing any inadequacies or inconsistencies in the APD data submitted and requiring corrective actions. Any third-party health care payer that receives an audit report or statement of deficiencies shall submit a plan of correction to the Department within 30 days from the date of receipt of the audit report or statement of deficiencies. Third-party heath care payers shall be in full compliance with APD data submission specifications and the plan of correction within 90 days from the date of submission of the plan of correction.

(h) A third-party health care payer may submit a written request to the Department for an extension, variance, or waiver of APD data submission specifications requirements. The written request shall include: the specific requirement to be extended, varied, or waived; an explanation of the reason or cause; the methodology proposed to eliminate the need for future extension, variance, or waiver; and the time frame required to come into compliance.

(i) Any third-party health care payer that violates this section shall be liable pursuant to the provisions of the Public Health Law, including, but not limited to, sections 12 and 12-d of the Public Health Law, and applicable sections of New York State Insurance Law and regulations.

§ 350.3 APD data release.

(a) The Department shall implement quality control and validation processes to provide reasonable assurance that APD data released to the public is complete, accurate, and valid. The Department shall adhere to applicable State and federal laws, regulations, and policies on release of Medicare and Medicaid data.

(b) Upon reasonable assurance that subdivision (a) has been satisfied, the Department may release data in the following manner:

(1) De-identified and/or aggregated APD data of a public use nature may be posted publicly to a consumer facing website.

(2) APD data, including data with identifying data elements, may be released to a New York State agency or the federal government in a manner that appropriately safeguards the privacy, confidentiality, and security of the data.

(3) APD data, including data with identifying data elements, may be released to other data users that have met the Department's requirements for maintaining security, privacy, and confidentiality and have approved data use agreements with the Department.

(c) Data users shall adhere to security, confidentiality, and privacy guidelines established by the Department to prevent breaches or unauthorized disclosures of personal information resulting from any data analysis or re-disclosure. Data users bear full responsibility for breaches or unauthorized disclosures of personal information resulting from use of APD data.

(d) (1) Where the Department grants data users access to APD data that does not include identifying data elements, such access shall be subject to terms and conditions established by the Department.

(2) Data users who wish to request APD data that includes identifying data elements shall submit an application for a proposed project in a form established by the Department, which shall include an explicit plan for preventing breaches or unauthorized disclosures of identifying data elements of any individual who is a subject of the information. The Department's review of the proposed project shall include, but not be limited to: (i) use of the specific identifying data elements; (ii) adherence to the Department's guidance on the appropriate and controlled release of data; and (iii) assurance on whether the release of identifying data elements reflects overall goals of confidentiality, privacy, security, and benefits to public and population health.

(e) Any data user that violates this section or any data use agreement executed under this section shall be liable pursuant to the provisions of the Public Health Law, including, but not limited to, sections 12 and 12-d of the Public Health Law.

(f) The Department may charge reasonable fees for access to APD data, which shall be based upon estimated costs incurred and recurring for data processing, operation of the platform/data center, and software. The Department shall establish a policy describing any APD data that shall be available at no charge, the fees for access to APD data subject to charge, the process for fee payment, and under what circumstances fees may be reduced or waived.

§ 350.4 APD advisory group.

(a) The Department may establish an advisory group to provide recommendations on any or all of the following areas: submission specifications, patient privacy and confidentiality, data release, data aggregation, and security.

(b) The Department may accept, reject, or amend recommendations, in whole or in part, from the advisory group.

§ 350.5 APD guidance.

The Department shall make guidance available on its website that includes:

(a) APD submissions specifications, including the data standards used and the method for reporting to the Department. Submission specifications shall be developed with a goal of minimizing burden on health care providers and third-party health care payers, including utilization of nationally standardized file formats where available and feasible.

(b) APD data access and release policy, including security and usage requirements to become a data user; requirements for maintaining privacy, confidentiality, and security; and data release fee information. Data access and release requirements shall include restrictions on the release of any information that could be

used, alone or in combination with other reasonably available information, to identify an individual who is a subject of the information, as well as procedures for request of identifying data elements, including the project application process established pursuant to subdivision (d) of section 350.3 of this Part.

(c) Program operations policy, including program purpose, scope and objectives, and general governance.

## REGULATORY IMPACT STATEMENT

**Statutory Authority:**

Public Health Law (PHL) § 2816 establishes the Statewide Planning and Research Cooperative System (SPARCS), which authorizes the New York State Department of Health to collect certain data relating to health care delivery in New York State. In particular, the statute authorizes the Department to collect data relating to insurance claims by persons covered by third-party insurers (hereinafter referred to as "payers"). The statute further provides: "Any component or components of the system may be operated under a different name or names, and may be structured as separate systems."

Accordingly, PHL § 2816 authorizes NYSDOH to collect covered person data and claims data in its All Payer Database (APD). Additionally, under PHL § 206(18-a)(d), the Commissioner of Health has the authority to "make such rules and regulations" on statewide health information systems, such as the APD, as recommended by the Health Information Technology Workgroup established pursuant to PHL § 206(18-a)(b)(ii).

**Legislative Objectives:**

In 2011, PHL § 2816 was amended specifically to authorize NYSDOH to develop and implement an All Payer Database for New York State. The Legislature further authorized NYSDOH to develop regulations establishing the necessary parameters, guidance, and requirements for a functional APD. These regulations are critical to the

successful collection and use of covered person data and claims data from commercial health care payers, which have previously not been done in New York State.

**Needs and Benefits:**

Currently, New York State has fragmented, inconsistent, and incomplete information about how the state's health care system is performing. With an array of state agencies and offices carrying out health care planning, along with a myriad of private efforts, data currently collected are specific to the goals of the distinct organization and sub-populations served.

This approach is administratively inefficient and costly, as it requires the redundant collection, cleansing, and storage of duplicative information. The lack of linkages and interoperability of data assets hinders the ability of health care and policy experts to fully assess issues, such as the impact of disease burden and treatment trends, the ability to inform policy on innovative payment and care coordination models, and other targeted interventions.

Advancing health care transformation in New York State requires a broad view of population health and system performance, which current data resources do not permit. States that currently have All Payer Claims Databases (APCDs) have proven that they are important tools for filling gaps in health care information. By streamlining health care system data processing, an APD will enable policymakers to monitor efforts to reduce health care costs and improve population health.

The APD will provide a robust dataset that will support a variety of comparative analyses. Further, the APD will transform New York State's health care system by

evaluating care delivery and payment models, and identifying opportunities to avoid waste, over/under utilization, misuse of treatments, and conflicting plans of care.

The APD will also yield findings that can be used to inform health care and finance decisions for policy makers, payers, providers, and consumers. For example, the APD will facilitate assessments of health care resource needs. APD data can also be used to effectively plan for and improve disease prevention, and to help ensure effective diagnosis, treatment, and rehabilitation services. APD data will allow the State to establish policies for risk adjustment, including mandatory risk adjustment calculations under the Federal Patient Protection and Affordable Care Act. In addition, the APD will enhance and expedite the ability of health payers and regulators to prescribe and determine appropriateness of premium rates.

**Costs:**

**Costs to Regulated Parties:**

Many health care insurance payers are already required to submit claims and records of care encounters to New York State. These include payers that have plans included in Medicaid Managed Care and in the New York State of Health Official Health Plan Marketplace (NYSoH), both of which require data submission as part of contractual agreements to participate in their respective programs. In addition, many payers voluntarily participate with private regional claims database initiatives, or submit data to other state APCDs.

Many of these public insurance program participants are also payers of commercial insurance plans, which lack access to claims history, and which have no

other mechanisms to mandate data submission. As a result, many of the payers participate in both public and private programs that involve some form of data submission.

For this reason, much of the staffing and information technology (IT) infrastructure required for mandatory participation in New York State's APD is already in place. There may be some initial increased implementation costs for payers who only participate in the private commercial market. Payers that currently report data in a proprietary format may also be exposed to costs associated with transitioning to a national standardized reporting format. However, because so much of the IT infrastructure is already in place, it is anticipated that regulated parties' long term costs associated with a fully functional APD will be minimal.

**Costs to the NYSDOH:**

As referenced in the prior section, many health care insurance payers are already required to submit claims and records of care encounters to New York State. While there is some infrastructure currently in place within NYSDOH, there is still a NYSDOH cost for the design, development, and implementation of infrastructure to operate the APD.

Costs include major system components of data intake, data warehousing, and data analytics, with a current estimate of $55 million for a three and a half-year development period. Following this development, the annual recurring operating costs for the system is estimated to be $20 million, inclusive of annual recurring NYSDOH staff costs of approximately $2 million. Total costs are covered by a combination of State appropriations, federal matching Medicaid and Child Health Plus funds, and federal Health Benefit Exchange grants.

Other systems in the NYSDOH, and the expenditures required to maintain them, will be partially reduced as the APD will assume some of the functions associated with them.

**Costs to State and Local Governments:**

There are no anticipated costs to local governments, as the APD will be fully developed and administered at the State level. There are minimal costs that may be incurred by the NYS Department of Financial Services to utilize the data and tools of the APD in the regulation of the commercial health insurance industry. These are not expected to be significant, however, and will be offset by the utility achieved through analysis of health insurance claims data.

**Local Government Mandates:**

The All Payer Database will be administered at the New York State level. This rule imposes no mandates upon any county, city, town, village, school district, fire district, or other special district.

**Paperwork:**

Payers will be required to submit registration forms and paperwork to NYSDOH or its designated administrator in order to submit claims data with protected information to the State. This paperwork is only required for initial registration with the APD, and subsequent communication is handled electronically. For this reason, the reporting requirements, forms, or other paperwork upon regulated parties are not expected to be a significant burden.

**Duplication:**

There are no relevant rules or other legal requirements of the federal or State governments that duplicate, overlap, or conflict with this rule.

**Alternatives:**

There are no alternatives that could serve as a substitute for the All Payer Database. Although New York State currently collects Medicaid and NYSoH data, the collection of commercial claims data is unprecedented. The APD is a significant new initiative that will allow for a comprehensive and valuable analysis of the health care system in New York State.

**Federal Standards:**

The rule does not exceed any minimum standards of the federal government for the same or similar subject area as the federal government does not operate an All Payer Database.

**Compliance Schedule:**

Development of the APD data intake component is being executed in a phased manner. The first phase included NYSoH Qualified Health Plans, and data collection began in January 2015. The second phase encompasses Medicaid and Child Health Plus Managed Care Plans, which went into production September 2015.

The third phase addresses commercial health insurance payers and the design and development process has already begun. This information is critical to the success of the APD. It is expected that production will begin for commercial payers in late 2016, with substantial attention to testing and user support to ensure all payers have the necessary tools to successfully participate.

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## STATEMENT IN LIEU OF

## REGULATORY FLEXIBILITY ANALYSIS

No regulatory flexibility analysis is required pursuant to section 202-b(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments and it does not impose reporting, record keeping, or other compliance requirements on small businesses or local governments.

## STATEMENT IN LIEU OF RURAL AREA FLEXIBILITY ANALYSIS

A Rural Area Flexibility Analysis for these amendments is not being submitted because amendments will not impose any adverse impact or significant reporting, record keeping, or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

## JOB IMPACT STATEMENT

**Nature of Impact:**

The rule will have minimal impact on jobs and employment opportunities. The regulated payers are largely established. In many cases, they are national health insurance companies that have an existing and deep data reporting infrastructure per the nature of the industry.

Many payers already report certain claims data to NYS and, with the APD, will now be required to send a higher volume. There may be some increase in hiring and jobs to ensure compliance with APD requirements; however, this impact is not expected to be significant. Much of the infrastructure already exists and many payers already submit data to public health insurance programs, regional voluntary databases, and other state APCDs. There will be some impact on employment in the IT contracting field as there will be contracts with NYSDOH to design, develop, implement, and operate the APD at the state level, as well as potential IT development work with some of the payers. There are no anticipated job impacts in any other segments or sectors of the job market. With regard to adverse employment effects, there is no expectation of job losses as a result of the rule.

**Categories and Numbers Affected:**

The types of jobs impacted by the rule are in the areas of IT and data analysis. The number of expected job additions is not specifically known but is expected to be minimal as payers have much of the existing resources needed to comply with data submission requirements. Most new work on the part of payers will be in the initial stages

of implementation. Payers that do not currently submit data to NYS will need to establish processes and set up IT systems to submit claims data.

Certain payers will have some level of system modification to comply with national standards and submission specifications. Some payers will utilize contract vendors for these activities who may already be familiar with the required transaction and buildout processes. IT contractors at the state level will see a short term increase for the design, development, and implementation of the system build, but ongoing operations support will rely on less staffing.

**Regions of Adverse Impact:**

There is no expectation of adverse impact on jobs in any region of NYS as a result of the rule.

**Minimizing Adverse Impact:**

There is no expectation of adverse impact on jobs in any region of NYS as a result of the rule.

**Self-Employment Opportunities:**

There is no expectation of any self-employment opportunities.