

In This Issue:

Final Deadline for Regulated Entities to Implement Protections Under Department of Financial Services' (DFS) Cybersecurity Regulation

State Department of Health Shares Stories of DSRIP Impact in Patient Health

HHS Proposes Rule to Eliminate Rebates on Prescription Drugs in Medicare Part D and Medicaid Managed Care

Medicaid Program January 2019 Updates and Releases

VBP Updates

Regulatory Update

Legislative Update

Calendar

Quick Links

Final Deadline for Regulated Entities to Implement Protections Under Department of Financial Services' (DFS) Cybersecurity Regulation

Last week, DFS Superintendent Maria T. Vullo provided a [reminder](#) to all DFS-regulated entities and licensed persons covered by the Department's [cybersecurity regulation](#) that the final implementation period for the regulation ends March 1, 2019. The cybersecurity regulation became effective March 1, 2017 and DFS implemented a two-year timeline for implementation of the regulation's requirements, with a final compliance deadline of March 1, 2019.

The final step in the implementation timeline requires regulated entities that use third-party providers to put policies and procedures in place ensuring the security of information systems and nonpublic information. Additionally, the reminder includes, that all regulated entities must submit the second [certification of compliance](#) for the prior calendar year electronically via the [DFS cybersecurity portal](#) on or before February 15, 2019. For additional cybersecurity resources, visit the [DFS Cybersecurity Resource Center](#).

State Department of Health Shares Stories of DSRIP Impact in Patient Health

The Department of Health recently released a [storybook of highlights](#) of the [Delivery System Reform Incentive Payment \(DSRIP\)](#) waiver, capturing a handful of examples of transformative changes taking place in healthcare across the State. According to DOH, the State is currently seeing a 17% reduction in preventable hospital admissions as a result of DSRIP efforts.

HHS Proposes Rule to Eliminate Rebates on Prescription Drugs in Medicare Part D and Medicaid Managed Care

Last week, the Secretary of HHS published a [proposed rule](#) intended to eliminate the payment of rebates by drug manufacturers on prescription drugs to Part D plan sponsors, Medicaid Managed Care plans, and pharmacy benefit managers (PBMs) who contract on behalf of these organizations.

The proposal follows the President’s “[Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs](#)” which is designed to eliminate the use of rebate payments in Medicare Part D and Medicaid Managed Care. HHS believes that the current rebate framework may be increasing financial burdens for beneficiaries as rebates do not always flow through to consumers with cost sharing obligations, while list prices have increased substantially over time along with rebate amounts, creating what has been referred to as a “gross to net bubble”.

The proposed rule would prohibit rebates by eliminating the existing regulatory safe harbor that currently exempts rebates from otherwise being classified as kickbacks in violation of the Federal Anti-Kickback statute. Only rebates payable to Medicare Part D and Medicaid MCOs would be prohibited under the proposed rule; rebates payable to other entities, such as physicians, pharmacies, and third party payors in other commercial or Federal health care programs (e.g., Medicare Part B FFS, a Medicaid managed care program operating under 1915(b) Waiver Authority, etc.) would continue to remain exempted under the existing safe harbor. Of note, HHS has invited comment on whether the definition of a Part D plan sponsor should be expanded to include PACE organizations offering a PACE plan including qualified prescription drug coverage.

In addition to eliminating the safe harbor protecting rebates, the proposed rule also adds a safe harbor to protect discounts provided to patients at the point of sale at a pharmacy. Another safe harbor would be added to protect fixed fees that manufacturers pay to PBMs for services rendered for specified criteria.

Medicaid Program January 2019 Updates and Releases:

New Resource:

Medicaid Pharmacy Program Opioid Management Webpage and Non-Opioid Alternative Chart - The Medicaid Pharmacy Program has developed a [webpage](#) that provides links to resources for the treatment of substance use disorder and the use of opioids/non-opioids for the management of pain. Additionally, the State Department of Health has developed the [reference chart](#), “Medicaid Non-Opioid Alternative Treatment Options,” to aid in selecting non-opioid treatment options for the management of pain. This chart lists FDA/Compendia-supported medications that can be used for pain management.

Policy and Billing Updates:

Transportation Provider Record Keeping Requirements: Use of Electronic Driver Signatures - Currently the Department requires that the records kept by participating Medicaid transportation providers include: (1) the full printed name and signature of the driver providing the transport, and (2) the signed attestation of the driver that the trip was completed. ***Effective February 1, 2019***, the Department will allow (1) substituting the written signature of the driver providing the transport with a unique identifying electronic signature, and (2) requiring drivers attest that the trip has been completed by using an electronic verification transmission that records both the trip drop-off and pick-up destination coordinates. For additional details, including details for Ambulette, Taxi/Livery Providers, click [here](#).

Pharmacy:

NYS Medicaid Fee-for-Service Retroactive Repricing Per Prior Changes Made to Pharmacy Reimbursement –As result of reimbursement methodology changes from the CMS Covered Outpatient Drug Final Rule effectuated on April 1, 2017 the Department will start to process claims adjudicated effective April 1, 2017 through February 21, 2018, in which DOH anticipates will span several months and estimated completion by December 2019. For further detail click [here](#).

All Providers:

NY Medicaid Billing Training Available to Providers - Training sessions are available at no cost to providers and include information regarding claim submission, Medicaid Eligibility Verification System (MEVS), and using the eMedNY website. [Seminars](#) - are conducted as in-person training sessions with groups of providers and billing staff and are available at various locations throughout New York State. [Webinar](#) training sessions are also available online.

New York Medicaid EHR Incentive Program – The Medicaid Electronic Health Record (EHR) Incentive Program promotes the transition to EHRs by providing financial incentives to eligible professionals (EPs) and hospitals. EHR systems are leading the way towards interoperability to exchange and use patient health records electronically. Since the start of the program in 2011, 37,398 payments totaling almost \$1 billion have been distributed to Eligible Professionals & Eligible Hospitals. For additional details on registering as an EP, click [here](#).

Children’s Medicaid Health and Behavioral Health System Transformation Update - February 2019

The Department of Health recently released the February 2019 Children’s Medicaid Health and Behavioral Health System Transformation Update. This Issue #04 includes:

- Current Children’s Services and Timeline Update;
- Supporting Materials;
- Webinars; and
- Links to Prior Trainings and Releases.

This update will soon be posted on the Department [website](#) (under “... Updates” tab).

VBP Updates

2019 Children’s VBP Quality Measurement Set

The Children’s [VBP Quality Measure Set for Measurement Year \(MY\) 2019](#) is now available on the [VBP Resource Library section of the website](#). According to the instructions, the Children’s Measure Set is applicable to any Total Care for General Population (TCGP),

Integrated Primary Care (IPC), or Pediatric Primary Care Capitation (PPCC) VBP arrangement. Compared to the Children's Measure Set for MY 18, the MY 19 set includes one additional Category 1 measure (asthma medication ratio), bringing the total Category 1 measures to 19, and maintains the same Category 2 measures (7 in total).

Regulatory Update

Department of Health

Inpatient Psychiatric Services

The Health Department has issued a [notice of adopted rulemaking](#) to enhance reimbursement mechanisms for inpatient psychiatric services. The amendment modifies the definition of rural, resulting in an increase to the number of providers who qualify for additional reimbursement under the rural designation. It will also provide a 10% increase to the statewide base price for facilities that are located in an upstate region as defined within the regulations. The Department of Health has indicated that there will be no additional costs incurred by private regulated parties and the additional costs to the State have been allocated in the 2014-2015 Enacted Budget and therefore impose no additional expenditures to the State.

The rule, as adopted, contains non-substantive changes were made in section 86-1.39(e)(2), (5), (6) and (o), of the proposed rule that published in the [June 20, 2018](#) edition of the NYS Register.

The adopted rule is effective as of January 30, 2019.

Statewide Planning and Research Cooperative System (SPARCS)

The Health Department has issued a [notice of adopted rulemaking](#) to revise the SPARCS regulation related to data intake. This rule making revises Section 400.18 of Title 10 of the NYCRR, to grant the SPARCS program the flexibility to explore other data intake options, consistent with Public Health Law § 2816. This rule making also removes all references to Patient Review Instrument (PRI) data, which is an obsolete data source.

The rule, as adopted, contains no changes from the proposed rule that was published in the [August 22, 2018](#) edition of the NYS Register.

Midwifery Birth Center Services

The Health Department has issued a [notice of proposed rulemaking](#) to set the standards for all free-standing birth centers to follow the structure of Article 28 requirements. This regulation implements Chapter 397 of the Laws of 2016, which was intended to remove barriers that restrict the establishment of freestanding birth centers led by licensed midwives and permits the Department to determine, with consultation, which Article 28 certificate-of-need (CON) requirements are appropriate and reasonable. Education Law requirements governing the practice of midwifery will continue to apply to all midwives, regardless of the practice setting. There are currently only three freestanding birth centers in New York.

The proposed rule is open to public comment for sixty days, beginning January 30, 2019 as posted in the New York State Register.

Medicaid Reimbursement of Nursing Home Reserved Bed Days

The Health Department has issued a [notice of revised rulemaking](#) relating to reserved bed payments made by Medicaid to nursing homes. Chapter 57 of the Laws of 2017 recently amended Public Health Law (PHL) § 2808(25), which places limits on the availability of Medicaid payments to nursing homes, to reserve a bed for a Medicaid recipient 21 years of age or older who is temporarily absent from the facility.

The Department has taken into consideration the public comments provided by various stakeholders, including representatives of skilled nursing facilities (SNF) and nursing homes. This version of the proposed rule would make clear that Medicaid will not pay to reserve a bed for a recipient in a nursing home who is 21 years of age or older and temporarily hospitalized unless the recipient is receiving hospice services in the facility.

The **revised** rule contains substantial revisions made in sections 505.9(d)(1), (2), (6), (i), (7), 86-2.40(a) and (ac)(4) of 18 NYCRR, compared to the original proposed rule that was published in the [February 14, 2018](#) edition of the NYS Register.

The **revised** rule is open to public comment for forty-five days, beginning January 30, 2019 as posted in the New York State Register.

Department of Education

Administration of Certain Vaccines by Pharmacy Interns

The Department of Education has issued a notice of [emergency rulemaking](#) to implement chapter 359 of the Laws of 2018 (chapter 359), which amended Education Law section 6806, effective December 7, 2018, to allow the administration of immunizations by a pharmacy intern, certified to administer immunizations, under the immediate and personal supervision of a licensed pharmacist certified to immunize. Chapter 359 was enacted, in part, to make immunizations more readily available and to provide certified pharmacy interns with valuable hands on clinical experience, while under the oversight and supervision of a licensed pharmacist, who is certified to administer immunizations. This notice is intended to serve as both a notice of emergency adoption and a notice of proposed rulemaking. The emergency rule will expire April 14, 2019.

The proposed rule is open to public comment for sixty days, beginning January 30, 2019 as posted in the New York State Register.

Legislative Update

The Legislature will be in session Monday and Tuesday this week and have commenced their [joint budget hearings](#) scheduled through February 12th, the Health and Medicaid hearing is scheduled for 9:30 am on February 5th.

The following bills of interest have been placed on committee agendas this week:

Assembly Insurance

- [A1619 \(Rozić\)](#): This Bill would amend insurance coverage requirements for eating disorders by defining “eating disorder” as any eating disorder contained in the most recent Diagnostic and Statistical Manual of Mental Disorders (DSM).

Assembly Health

- [A1084 \(Gottfried\)](#): This Bill establishes the right of a resident of an Adult Care Facility (ACF) to be fully informed of their condition and medication and treatment plan, and

expressly provides resident's with the right to refuse medication or treatment included in their treatment plan. The Bill provides that operators acting reasonably and in good faith cannot be held liable for complying with a resident's refusal of medication.

- [A1147 \(Gottfried\)](#): This Bill would require establishment approval by the Public Health and Health Planning Council (PHHPC) for entities exercising "passive" powers over an established operator, otherwise known as a "passive parent".
- [A2345 \(Solages\)](#): This Bill would authorize Medicaid coverage for lactation support, care and services, including breastfeeding equipment when provided by a qualified lactation care provider. Currently, Medicaid coverage for lactation support requires that it be ordered by a physician, physician assistant, nurse practitioner, or licensed midwife in order to be covered under Medicaid.

Calendar

Tuesday February 5,
2019

2019 Health and Medicaid Joint Legislative Hearing
9:30 a.m.
Hearing Room B, Legislative Office Building, Albany

Tuesday February 12,
2019

NY Medicaid EHR Incentive Program Webinars ([More Details](#))
2:00 p.m.
Please sign up [here](#) to join this event.

Thursday, February
14, 2019

The Bureau of Tobacco Control and The New York State Tobacco Use Prevention and Control Advisory Board -- Video conference
9:00 a.m. to 3:00 p.m.
ESP Corning Tower Building, 2876A Conference Room, Albany, NY

The Drug Utilization Review Board (DURB)
9:00 a.m. to 4:00 p.m.

QUICK LINKS

[NYS Department of Health](#) --- [NYS DOH –Meetings, Hearings & Special Events](#) --- [Medicaid Redesign Team](#) --- [Senate Health Committee Website](#) --- [Assembly Health Committee Updates](#) --- [NYS Division of Budget](#)

Plugged in to Health at Hinman Straub is prepared by Hinman Straub P.C. and is intended to keep our clients informed about health news and Legislative and regulatory developments that may affect or otherwise be of interest to them. The comments contained herein do not constitute legal opinion and should not be regarded as a substitute for legal advice. If you prefer not to receive these updates, please alert us so we may remove you from our distribution list. © Hinman Straub P.C. 2019. All rights reserved.

