New York State of Health Law: Trendsetter or Over-Regulator?

A program offered by the New York State Bar Association Health Law Section, in conjunction with the American Health Lawyer's Association

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New York Hilton
Grammercy Suite
5:00-6:00 p.m.

Latest legislative and regulatory developments

- Out of network coverage access
- Nonprofit Revitalization Act
- Package of heroin addiction-related initiatives
- Other health-related legislation in closing days
- Soda ban case
- ACO regulation
- DSRIP
- COPA and DSRIP regulatory reforms
- Medical marijuana
- CON changes

NON-PROFIT REVITALIZATION ACT

- First major revision to the NY Not-for-Profit Corporation Law in over 40 years
- Signed by Governor Cuomo in December 2013
- Effective July 1, 2014

Streamlines creation of not-for-profits

- No longer Types A, B, C and D corporations
- As of July, there will be only “charitable” and “non-charitable” not-for-profit corporations
- No longer necessary to specifically described planned activities in certificate of incorporation
- Department of State may correct non-material errors in certificates of incorp. on request

Audit committee/oversight

- NFPs that must file an annual independent CPA audit report with the AG (i.e., those with gross revenues over $500,000 as of July 1, 2014) must have an audit committee, or audit oversight by full board (with defined duties)
  - Audit committee must be all “independent directors”
    - Not employed or relative of employee within last 3 years
    - Not received or have relative with direct comp from corp. or affiliate or more than $10,000 within last 3 years
  - If full board, only independent directors may participate

Conflict of interest policy

- Every NFP must have a conflict of interest policy that includes at least:
  - Description of conflict
  - Procedures for disclosing and addressing
- Directors must disclose potential conflicts prior to election and at least annually thereafter
- Also, related parties must disclose and not participate in deliberations or vote

Whistleblower policy

- Not-for-profits with 20+ employees and annual revenue over $1 million must adopt a whistleblower policy to protect persons who report suspected improper conduct from retaliation
- Policy must be distributed to all employees, directors and officers
- Must designate someone to administer the policy and report to the board or audit comm.

Real Estate Transactions

- No longer need in all cases for 2/3 majority vote of Board for any real estate transaction
- Purchase, sale, mortgage, lease, exchange or disposal of real property
  - If not “all or substantially all” of assets: majority of board allowed, or delegation to committee
  - If “all or substantially all” of assets
    - Boards under 20: 2/3 vote of entire Board
    - Boards of 20+: majority of entire Board

Approval of mergers, etc.

Approvals of

- merger, consolidation
- disposal of all or substantially all assets

One-step approval process available with Attorney General's office

Court approval no longer necessary

Notices and votes

- Email or fax allowed for:
  - Member meeting notices
  - Waivers of notice of meeting by members and directors
  - Authorization of member proxies
  - Consent to corporate actions by member vote
  - Unanimous written consent

OUT-OF-NETWORK BILLING LAW

- Part of New York State budget April 2014
- Effective 2015 and later
- Focus: increase transparency of billing, and avoid “surprise medical bills” for patients who don’t realize that providers are out-of-network
- Amends New York Insurance Law and Public Health Law

Requirements to disclose participating plans

- Health care professionals, group practices, diagnostic and treatment centers and health centers (on behalf of professionals) shall:
  - Disclose in writing or through the web the plans in which they participate and affiliated hospitals
  - Before non-emergency services
  - Verbally when appointment is scheduled

Out-of-network providers responsibility to inform

- If a professional or D&T or health center does not participate in a patient's plan:
  - Before non-emergency services, must inform patient that the amount or estimate is available on request
  - Upon request, disclose the amount or estimate (or schedule of fees if a health center) to be billed absent unforeseen medical circumstances

Physician offices & referral info

- Physicians shall provide name, address and phone # of any other physician
  - Whose services are arranged by the doctor for a patient scheduled to receive hospital services
    - And how to determine the other doctor's in-network plans
  - If care is in the doctor's office or referred by the doctor and the care is for
    - Anesthesia
    - Lab
    - Pathology
    - Radiology
    - Assistant surgery

Hospital required postings

- Hospitals must post on hospital website:
  - Standard charges
  - Participating health plans
  - Statement that physician services provided in hospital are not part of hospital charges
  - Statement that physicians in hospital may not participate in same plans
  - Contact information for contracted physician groups, including anesthesia, radiology, pathology

Hospital registration or admission material

Hospital material must:

- Advise patient to check with physician as to other physicians involved
- Whether anesthesia, pathology or radiology services are anticipated
- How to timely determine the health plans of physicians providing services at the hospital

Dispute resolution

- Dispute resolution process between out-of-network providers and insurers to hold patients harmless
- The New York Department of Financial Services will establishing standards for the process
- “Independent dispute resolution entities” will be comprised of licensed physicians in the same or similar specialties as the applicable provider.

Dispute resolution for emergency services

- Health plans must bill a “reasonable” amount for emergency services rendered by non-par physicians
  - And plan “shall ensure” that insured incurs no greater out-of-pocket costs than with a participating physician
- If a dispute, may be submitted to an independent dispute resolution entity
- Must choose one of the two bills, or if both unreasonable, promote settlement

“Surprise bills”

“Surprise bills”: bills from an out-of-network provider if:

(i) a participating provider was unavailable;

(ii) the services were by a non-participating provider without the patient’s consent or knowledge;

(iii) unforeseen medical services had to be rendered;

(iv) the patient was referred to a non-participating provider without the patient’s explicit written consent;
(v) an uninsured patient did not receive timely required disclosures.

Does not include bill if patient elected out-of-network care when a participating physician was available.

Non-par physicians and surprise bills

- If a patient assigns benefits for a surprise bill to a non-par physician who knows the patient is insured, the non-par physician may bill the patient only for a co-pay or deductible
- The plan must pay the billed amount or try to negotiate reimbursement with the non-par physician

Disputes of surprise bills

- If the plan and the non-par physician can't agree on a fee, the plan must pay an amount it determines reasonable, and either may submit to dispute resolution
- Dispute resolution entity must select either the plan's payment or non-par doctor's fee unless both represent unreasonable extremes
  - Then direct negotiation for settlement

Costs of dispute

- Dispute resolution entity's determination is binding on all of the parties
- The losing party must bear the costs of the dispute process
- If a settlement is reached, the parties will share the costs
- Dispute resolution intended to last 30 days

Heroin surge response: criminal elements

- Creates a new crime in the penal code of “fraud and deceit related to controlled substances” to crack down on doctor shopping, criminalizing behavior by those individuals who obtain or attempt to obtain a controlled substance or a prescription by misrepresenting themselves as a doctor or pharmacist, or presenting a forged prescription.
- Adds the “criminal sale of a prescription for a controlled substance or of a controlled substance by a practitioner or pharmacist” as a designated offense for purposes of obtaining eavesdropping warrants as well as adding the offense as a “criminal act” for the purposes of prosecuting enterprise corruption cases.
- Grants the Department of Health (DOH)’s Bureau of Narcotic Enforcement expanded access to criminal histories to aid its investigations of rogue prescribers and dispensers.
- Increases the penalties for the criminal sale of a controlled substance by a pharmacist or practitioner by making the crime a class C felony.

Heroin surge response: Overdose kits and educational initiatives

Improved Accessibility to Naloxone Anti-Overdose Kits to Help Save Lives:

- The legislation includes the following provisions to improve accessibility and ensure the proper use of naloxone – an overdose antidote – when administered:
- Requires that every naloxone anti-overdose kit include informational cards with the important information on how to recognize symptoms of an overdose; what steps to take, including calling first responders; and how to access services through OASAS.

Expanded Public Education Campaigns to Prevent Opioid and Heroin Use:

- Directs OASAS to undertake a public awareness and educational campaign utilizing public forums, media (social and mass) and advertising to educate youth, parents, healthcare professionals and others about the risks associated with heroin and opioids, how to recognize signs of addiction and the resources available to deal with these issues.
- Directs the State Education Commissioner to update the drug abuse curriculum every three years so that students have the most current and up-to-date information on coping with drug abuse and other substance abuse problems.

Heroin surge response: New treatment models

- Creates a new demonstration program aimed at designing a new model of care that would divert patients who do not need in-hospital detoxification, but still need treatment, to appropriate services and facilities. This program would provide alternative short term community based treatment, avoiding unnecessary emergency room costs as well as enabling OASAS to study the effectiveness of the new approaches to address the needs of individuals suffering with substance addiction.
- Directs OASAS to create a wraparound services demonstration program to provide services to adolescents and adults for up to nine months after the successful completion of a treatment program. These services would be in the form of case management services that address education, legal, financial, social, childcare, and other supports. These services will help former patients improve their quality of life and greatly reduce the likelihood of relapse.
- Provides that young people alleged to be suffering from a substance use disorder – which could make the youth a danger to himself or herself or others – can be assessed by an OASAS certified provider as part of Person In Need of Supervision (PINS) diversion services.

Heroin surge response: Insurance-related initiatives

- Conforms Insurance Law coverage requirements to federal parity requirements.
- Enables individuals requiring treatment to have access to an expedited appeals process and ensures that they are not denied care while the appeals process is underway.
- Improves access to care by requiring insurers to use recognized, evidence-based and peer-reviewed clinical review criteria, approved by the State Office of Alcoholism and Substance Abuse Services (OASAS), when making decisions regarding the medical necessity of treatment.
- Ensures medical necessity decisions are made by medical professionals who specialize in behavioral health and substance use.

Other 2014 health legislation

- Insurance coverage for telehealth
- Discharge information for visually impaired patients
- 21st Century Workgroup for disease elimination and reduction/Task Force on Disasters
- Eating disorder and Maternal depression initiatives
- Professional licensure/scope issues: CDTM for pharmacy, clinical lab personnel, dental faculty
- Graduate medical education initiative in Rochester

ACO Regulations

- State ACO legislation enacted as part of the April, 2011 State budget—amended further in 2012
- Regulations have been the subject of prolonged consideration and discussion within the Department of Health
- Regulations intended to clarify the roles of ACOs in New York with respect to approval process and conditions, operating requirements, contracting, risk-bearing authority, legal protections (i.e., antitrust scrutiny, fee-splitting and corporate practice issues)
- New revised draft regulations circulated in mid-May, 2014—and still not finalized.

Soda ban case

In the Matter of New York Statewide Coalition of Hispanic Chambers of Commerce, et al. v. NYC Dep't of Health and Mental Hygiene, Court of Appeals, June 26, 2014

- Challenged "Sugary Drinks Portion Cap Rule"
- September, 2012, NYC Board of Health adopted rule banning sale of sugary drinks in larger than 16 ounce containers
- Court upheld lower courts invalidation of the requirement, based largely on *Boreali v. Axelrod's* criteria that determine when administrative agency has "engaged in law-making and thus infringed upon the legislative" role
- Significant administrative law opinion, with potential consequences for other regulatory actions by local governments and State—and may have important implications for future public health interventions

DSRIP Overview

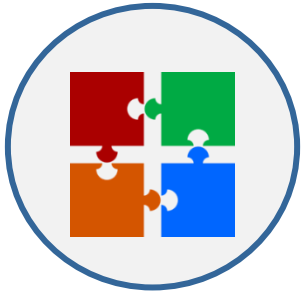
New York State (NYS) received federal approval to implement a Delivery System Reform Incentive Payment (DSRIP) program that will provide funding for public and safety net providers to transform the NYS health care delivery system.

Goals:

(1) Transform the safety net system

(2) Reduce avoidable hospital use by 25% and improve other health measures

(3) Ensure delivery system transformation continues beyond the waiver period through managed care payment reform



Key Program Components:

- Statewide funding initiative for public hospitals and safety net providers
- Only coalitions of community/regional health providers are eligible
- DSRIP projects based on a menu of interventions approved by CMS and NYS
- Payments to providers based on their performance in meeting outcome milestones and state achieving statewide metrics

DSRIP Program Components

Provider Eligibility and Patient Attribution

- Multiple safety net providers form coalition called “Performing Provider System” (PPS)
- PPS designates a “lead provider”
- ***Attribution*:** Assignment of Medicaid beneficiaries to PPS for measurement purposes (critical factor in determining potential performance payments to PPS)

Project Selection

- PPS select 5-10 projects from a CMS- and NYS-approved menu across three domains, which define specific strategies and metrics
- Projects are assigned scores based on relative potential to meet DSRIP goals
- Projects must respond to community needs and be new for PPS

Project Application and Project Valuation

- PPS submit letter of intent (project partners and geography)
- PPS submits DSRIP project plan (design funding available for development of plan)
- Plans reviewed by independent assessor, outside panel and state
- ***Valuation***: Five step process to score PPS projects and applications to calculate maximum performance payments available to PPS

Performance Payment

- Payment made based on achievement of project progress milestones and performance targets
- Performance improvement exceeding targets also eligible for additional bonus payments
- State must also demonstrate achievement of milestones or DSRIP payments are reduced across providers

DSRIP Projects Menu & Domains

Each DSRIP "Performing Provider System" selects at least 5 projects (and no more than 10 projects) from the following menu:

Domain 1: Overall Project Progress

Domain 2: System Transformation Projects (must include at least two projects)

- Create integrated delivery systems (required)
- Implementation of care coordination and transitional care programs
- Connecting Settings

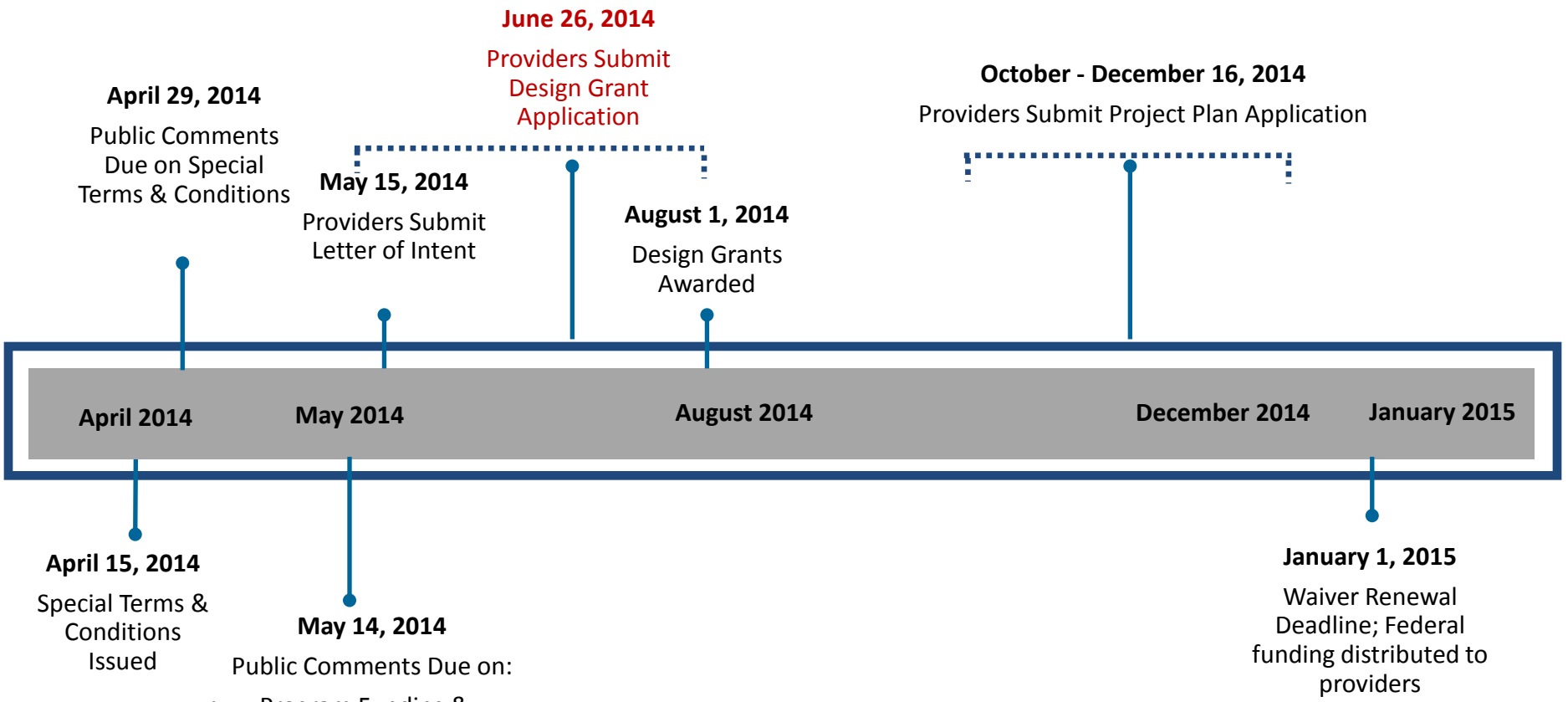
Domain 3: Clinical Improvement Projects (must include at least two projects)

- Behavioral health (required)
- Cardiovascular health
- Diabetes Care
- Asthma
- HIV
- Perinatal
- Palliative Care
- Renal Care

Domain 4: Population-Wide Prevention Projects (must include at least one project)

- Promote mental health and prevent substance abuse
- Prevent chronic diseases
- Prevent HIV and STDs
- Promote Healthy Women, Infants and Children

DSRIP Timeline and Key Dates

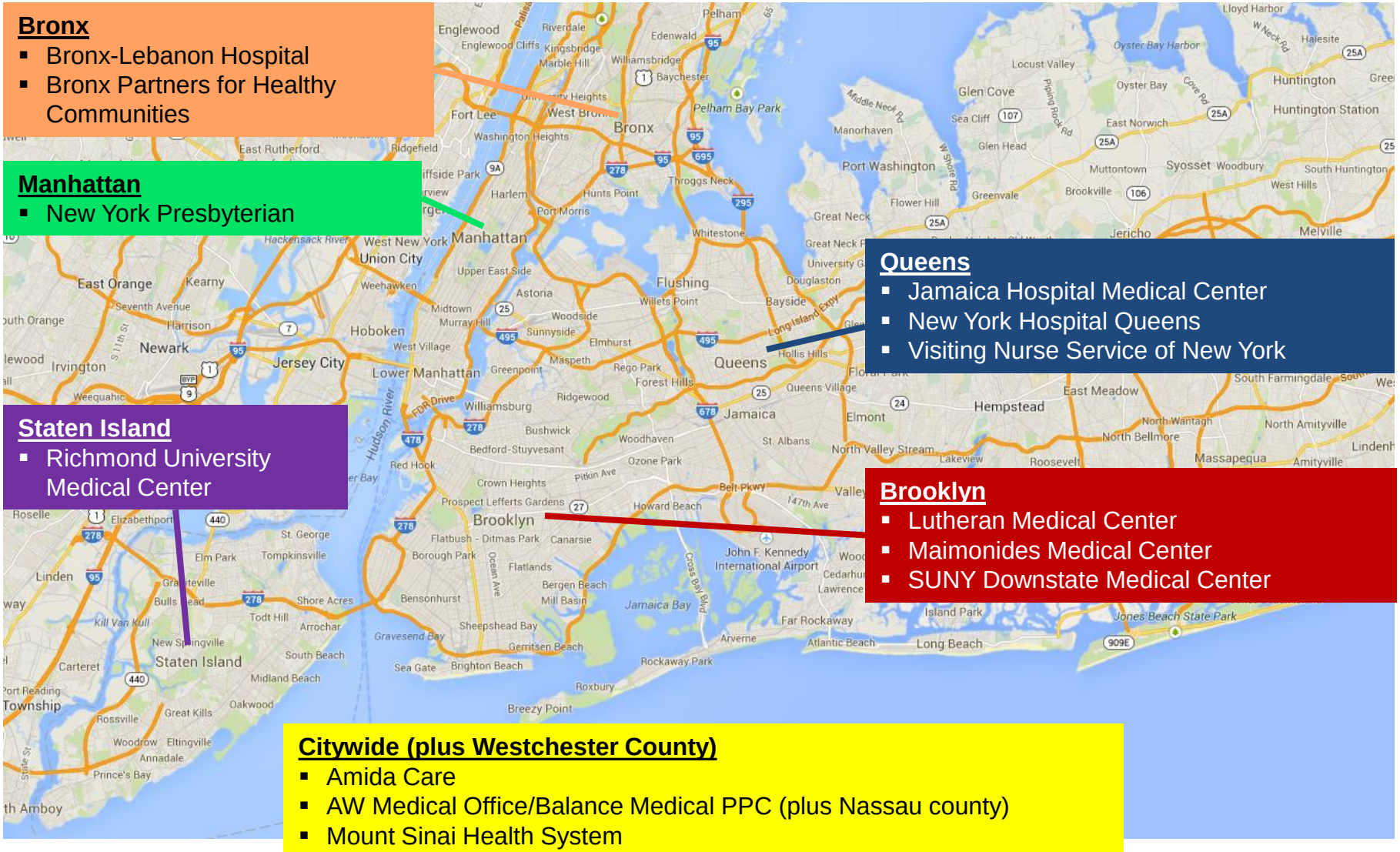


Other Dates:

Providers are required to submit quarterly reports on 8/30/14 and 11/30/14.

NOTE: Except for public comment deadlines, timeline is in flux. Reflects initial timeline released by NYS on 5/15/14

“Emerging” PPSs: New York City

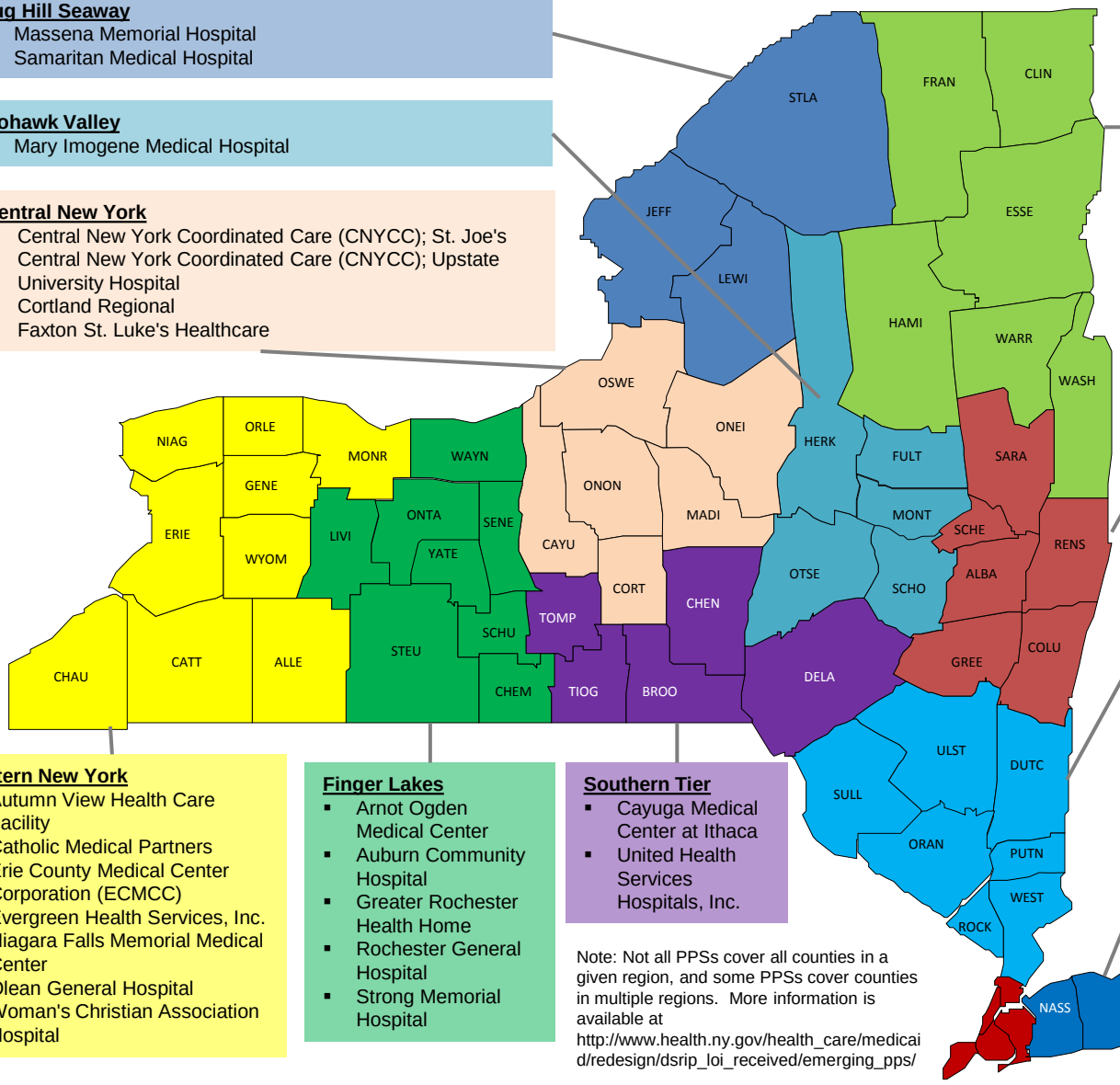


“Emerging” PPSs: Rest of State

Tug Hill Seaway
- Massena Memorial Hospital
- Samaritan Medical Hospital

Mohawk Valley
- Mary Imogene Medical Hospital

Central New York
- Central New York Coordinated Care (CNYCC); St. Joe's
- Central New York Coordinated Care (CNYCC); Upstate University Hospital
- Cortland Regional
- Faxton St. Luke's Healthcare



North Country
- Adirondack Health Institute

Capital Region
- Albany Medical Center Hospital
- Columbia Memorial Hospital
- Innovative Health Alliance of New York, LLC

Mid Hudson
- Health Quest
- Health Alliance of the Hudson Valley
- Montefiore Medical Center
- Refuah Health Center
- St. Luke's Cornwall Hospital
- Westchester Medical Center

Long Island
- Brookhaven Memorial Hospital Medical Center
- Catholic Health Services of Long Island
- Nassau Health Care Corporation
- North Shore - Long Island Jewish Health System
- South Nassau Communities Hospital
- Stony Brook Medicine

Western New York
- Autumn View Health Care Facility
- Catholic Medical Partners
- Erie County Medical Center Corporation (ECMCC)
- Evergreen Health Services, Inc.
- Niagara Falls Memorial Medical Center
- Olean General Hospital
- Woman's Christian Association Hospital

Finger Lakes
- Arnot Ogden Medical Center
- Auburn Community Hospital
- Greater Rochester Health Home
- Rochester General Hospital
- Strong Memorial Hospital

Southern Tier
- Cayuga Medical Center at Ithaca
- United Health Services Hospitals, Inc.

Note: Not all PPSs cover all counties in a given region, and some PPSs cover counties in multiple regions. More information is available at http://www.health.ny.gov/health_care/medicaid/redesign/dsrip_loi_received/emerging_pps/

DSRIP Issues

- Attribution methodology
- Alignment with Health Home/Medicaid managed care initiatives
- Consistency of quality standards
- Market power/Antitrust issues

Certificate of Public Advantage

- Certificate of Public Advantage (COPA)
  - Process for granting state action immunity under antitrust laws
  - State authority: Article 29-F of Public Health Law
    - April 2011 budget, based on March 2011 MRT rec
    - June 2011: Stakeholder workgroup
    - September 2013: Proposed regulations
    - Current focus: significant for some DSRIP PPS formation
    - Anticipating additional regulatory proposal

DSRIP: Regulatory Waivers

- Question 3.1 of Project Design Grant Application
- Do any regulations need to be waived to accomplish a DSRIP partnership within your emerging PPS?
  - Waiver authority granted in Budget
    - DOH, OMH, OPWDD, OASAS
    - "avoid duplication of requirements…allow efficient implementation of proposed project"
    - No waiver of patient safety
  - Focus on regulatory barriers
  - Consider transition points for patients moving through PPS
  - Learning process for all stakeholders
  - Regulatory barriers will likely emerge through PPS development

Ambulatory Services Oversight: Budget Proposals and Potential Regulations

Service	Recommendation/Proposal	Status
Limited Services Clinic ("Retail clinics")	• Create new provider type for retail settings • Allow corporate ownership • Develop regs: accreditation, disclosures to consumers, architectural review, link to primary care, limited services • PHHPC report: may operate as physician practice	• Proposed in Executive, Senate Budget Bills • Not in Assembly Bill
Urgent Care	• "Licensee practice" must be accredited, meet requirements to use term "urgent care" • Not construed to prohibit hospital from providing urgent care • PHHPC to develop regulations: scope of services, disclosure to consumers, link to primary care	• Proposed in Executive, Assembly Budget Bills • Not in Senate Bill
Freestanding ED (hospital-based only)	• Define name, standards, services • Require accreditation and CON review • Commissioner may use emergency powers • May operate part-time if at least 12 hours/day	• PHHPC recommended regulatory changes • Proposed in Assembly Budget; not in Exec, Sen
Advanced Medical Imaging	• Use of uniform language in accordance with Federal law • Require accreditation, expanded registration • Public education efforts	• PHHPC recommended regulatory changes
Radiation Therapy	• Enhance accreditation requirements • Expanded registration	• PHHPC recommended regulatory changes

Medical Marijuana: Background

Governor's January 2014 Announcement

- *"The program will allow up to 20 hospitals to provide medical marijuana to patients…with cancer, glaucoma, and other diseases…who are in a life-threatening or sense-threatening situation…and have been certified by a physician as meeting these criteria."*
- *"It will be subject to stringent research protocols…and be expected to fully comply with all applicable State and federal laws."*

Leveraging Existing NYS Law

- Antonio G. Olivieri Controlled Substances Therapeutic Research Program (PHL §3397 *et seq*.), established in 1980
- Commissioner seeks approval from FDA, acquires marijuana and provides to hospitals
- Physician recommends patient, hospital patient qualification committee reviews
- State board reviews hospital recommendations, can defer authority to hospital committee
- Current law considered inadequate by advocates: Gottfried/ Savino bill developed to create more comprehensive medical marijuana program.

Medical Marijuana: New Legislation

Compromise legislation supported by Governor Cuomo

- "Seed to sale" program, smoking prohibited
- "strike the right balance between...relieving…pain and suffering…and protecting the public against risks to its health and safety…"
- Broadly similar to existing programs in other states; arguably more tightly controlled
- Significant authority to DOH

Medical Marijuana: New Legislation

Patient certification

- Practitioner certifies patient
- Practitioner must be registered with DOH, have specific training
- Patient must be under practitioner's continuing care
- Practitioner to consider form patient should consume, dosage

"Serious condition"

- Cancer
- HIV/AIDS
- ALS
- Parkinson's
- MS
- Epilepsy
- Associated conditions including wasting syndrome, chronic pain, severe nausea
- Commish can add to lists

Registered organization

- For-profit or NFP organized for med mar-related purpose
- Must contract with independent lab to test product
- May sell to certified patient, caregiver; must file receipt in real time
- "Character/ competence" components

Implementation

- Effective in 18 months or when DOH/ State Police certify, whichever is later
- Registry identification cards
- Commish to determine price
- Legal protections for stakeholders
- 7% excise tax on gross receipts