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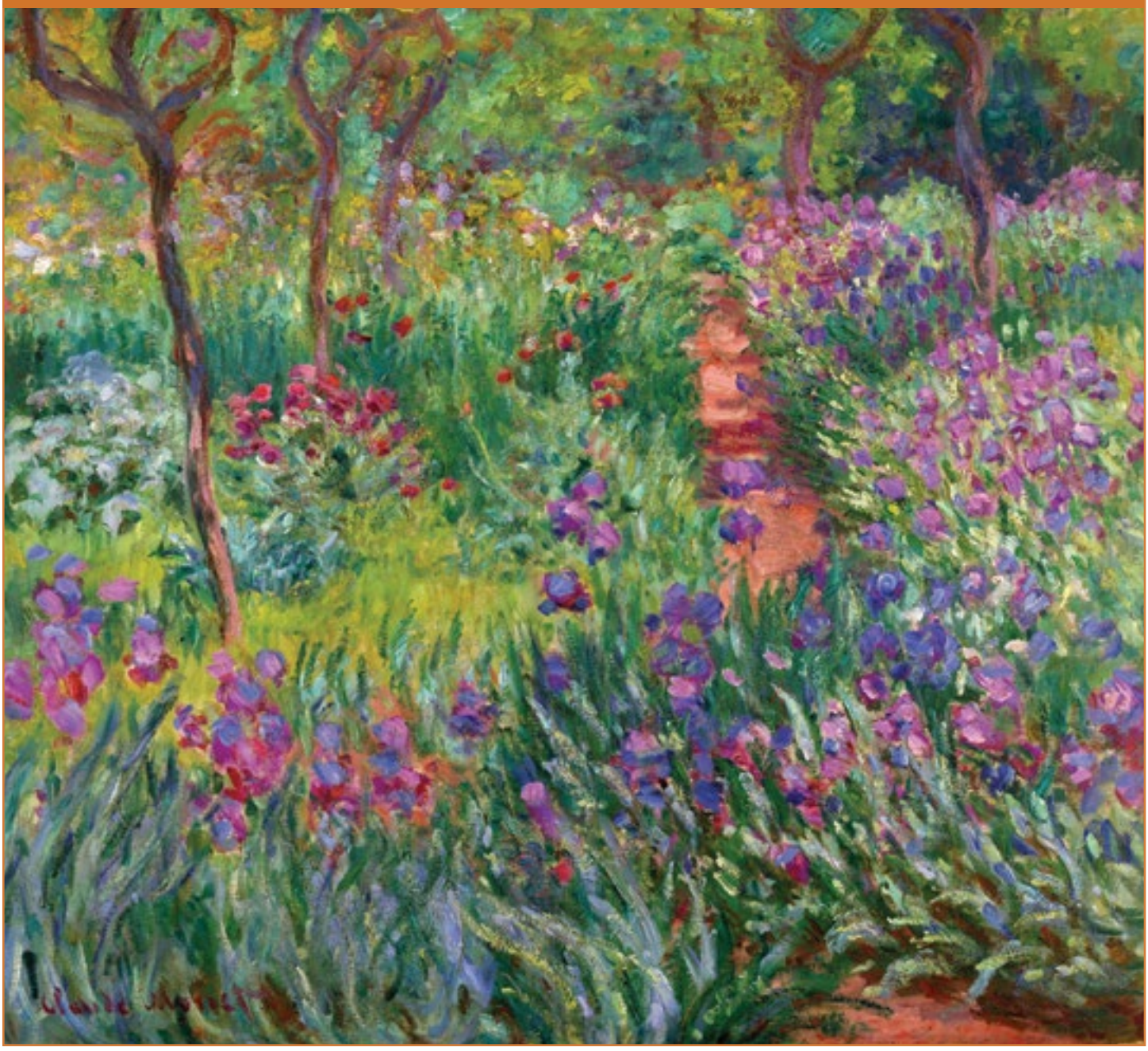
Special edition: DSRIP Performing Provider Systems



HEALTH LAW JOURNAL

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THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

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Cover artwork:
Claude Monet, *The Iris Garden at Giverny* (1900)

Message from the Section Chair

As I start this term as Chair my thoughts look forward to the upcoming year with the hope of continuing the strong structure of Section programs and involvement that has been built by past Chairs. The Section now has over 2,000 members. When I first joined in the early 1990s it was a small committee which met for lunch on a monthly basis in Manhattan. At each meeting there would be a talk by an industry leader or expert in health law issues. This structure was a precursor for the current committees within our Section.

During the course of my involvement with the Section I have benefited greatly from the educational programs developed by colleagues, treatises and updates focused on unique developments within health law in this state as well as opportunities to meet lawyers who are engaged with clients across the spectrum of health care. As our field has dramatically increased in complexity and depth the value of Section membership has grown exponentially.

Over the course of the coming months, our Section will continue its strong tradition of taking a leadership role within the changing health care environment. As in the past, our Section will assess regulatory and legislative changes, providing commentary from leading health care attorneys in the state for the benefit of public policy. As a prime example, this special edition of the *Health Law Journal* will address legal issues relating to Performing Provider Systems, formed in response to the DSRIP initiative. DSRIP is perhaps the most significant and ambitious health policy initiative in New York in recent years, and I congratulate Special Edition Editor Laurie Cohen for assembling an excellent array of articles on the topic.

We will also focus on integrating a network of law school health societies across the state into the Section's activities. As I write this column, I am preparing for a kick-off CLE conference to be held at Albany Law School on health information systems, electronic record exchange and the use of E-health and big data in clinical research and practice. This event is part of several year-long projects focused on surveying the law in various innovative areas of health care while providing a forum for CLE and publication of articles on the cutting-edge issues impacting our practice. The concept began in 2014 with a focus on telehealth and telemedicine. Each project will provide grants to summer law school interns to conduct research, ending with a symposium to bring it all together with speakers who are in the forefront of change within these fields. This year the program has expanded to include both Albany Law School and Fordham School of Law.

Please join me in venturing forward with the Section as we continue to grow and learn within our field, striving to meet the needs of our clients and inform public policy in a most critical area of social concern—our health.

Raul A. Tabora, Jr.

Chair

In the New York State Courts

By Leonard M. Rosenberg

Appellate Division Upholds New York's Criminal Ban Against Provision of "Aid-in-Dying" to Mentally Competent, Terminally Ill Patients

Myers et al. v. Schneiderman, 2016 WL 1948796 (1st Dep't 2016). Appellants, two patients, five medical professionals, and an advocacy group, appealed the New York County Supreme Court's dismissal of their action seeking to de-criminalize the provision of "aid-in-dying" to mentally competent, terminally ill patients who request such assistance.

Plaintiffs sought a declaration that the ban on physician-assisted suicide violates the Equal Protection and Due Process Clauses of the Federal and State Constitutions, and that, as a matter of statutory construction, the relevant Penal Law provisions are inapplicable to aid-in-dying. Plaintiffs emphasized the fact that over the last eighteen years, an increasing number of states and jurisdictions have legalized aid-in-dying through judicial decisions and legislation, and that "evolving medical standards and public views support aid-in-dying."

The Supreme Court granted Defendant's motion to dismiss the Complaint. While the Supreme Court disagreed with Defendant's contention that Plaintiffs lacked standing, the Court held that: (i) as written, the Penal Law is clear and concise, rendering unnecessary any analysis of its legislative history; and (ii) Plaintiffs' constitutional claims were controlled by *Vacco, et al. v. Quill et al.*, 117 U.S. 2293 (1997), which involved an identical action, and in which the Supreme Court recognized the constitutionally permissible distinction between the right to refuse medical treatment, and the right to commit suicide or receive assistance in doing so.

Plaintiffs contended that aid-in-dying is essentially indistinguishable from other medical practices that are universally not considered as suicide, and that numerous professional organizations and other states do not deem aid-in-dying equivalent to suicide. Plaintiffs further argued that, to the extent that the Penal Law does prohibit aid-in-dying, the law must be strictly scrutinized, and may only be narrowly tailored so as to advance a compelling state interest. Alternatively, Plaintiffs contended that the factual allegations of the Complaint were such that discovery should proceed on the issue of whether the relevant statutory sections were rationally tied to a legitimate state interest. Plaintiffs stressed New York's history of treating an individual's freedom of choice regarding her own body and medical treatment as vitally important, to be subordinated to the State's prerogatives under only compelling circumstances.

The Court held that the definition of the word "suicide," the act of taking one's own life voluntarily and intentionally, applied to aid-in-dying, since there is a direct causative link between the medication proposed to be administered and the patient's demise. The Court refused to interpret the statutes so as to recognize a distinction between suicide, which is a conscious choice of death over life, and aid-in-dying, which instead chooses quick and painless death over a longer and more painful death. Any such distinction, the Court held, must be provided by the Legislature, not the courts.

As to Plaintiffs' constitutional claims, the Court held that the distinction between the right to refuse unwanted medical treatment, and the right to seek aid-in-dying, is widely recognized. Citing numerous cases from the Court of Appeals, the Court noted that the cases on which Plaintiffs relied all involved a patient's right to refuse medical treatment, and were rooted in the same principles that give rise to a cause of action for medical malpractice due to lack of informed consent. Accordingly, the Court held that Plaintiffs had failed to overcome their burden of persuasion in arguing that the same principles applicable to the right to refuse medical treatment apply to the affirmative act of taking one's own life.

The Court also held that Plaintiffs had not demonstrated a societal evolution such that, if the ban on aid-in-dying were upheld, the Court would be "paying blind adherence to outmoded thinking." In particular, the Court noted that a number of the organizations Plaintiffs cited for their positions in favor of aid-in-dying have qualified their positions as existing alongside a wide range of views within their own memberships. The Court also noted that Plaintiffs asserted no change in the position of the American Medical Association that "physician-assisted suicide is fundamentally incompatible with the physician's role as healer."

Court of Appeals Holds That No Fault Insurers Are Not Required to Pay Facility Fees of Office-Based Surgery Practices

Government Empls. Ins. Co. v. Avanguard Med. Group, PLLC, 27 N.Y.3d 22 (2016). Appellant, an office-based surgical medical provider, appealed from an Appellate Division decision holding that no-fault insurer GEICO is not required to reimburse the provider for facility fees (charges for the use of a medical facility and its staff and equipment) under the no-fault insurance law. In an unanimous decision, the Court of Appeals affirmed the decision of the Appellate Division.

Pursuant to Insurance Law §5102(a), automobile insurers, like GEICO, must provide up to $50,000 of coverage for an insured's "basic economic loss." The statute provides that expenses for basic economic loss "shall be in accordance with the limitations of" Insurance Law §5108. That section authorizes the Chair of the Workers' Compensation Board to adopt fee schedules for basic economic losses, and mandates the Superintendent of the Department of Financial Services, in consultation with the Chair, to establish fee schedules "for all such services" not covered by the Chair's schedules. Where no fee schedule is specifically set forth in the Worker's Compensation fee schedules or established by the Superintendent, 11 NYCRR 68.5 provides a mechanism for setting such fees for necessary services. Based on this legal framework, the provider argued that pursuant to Insurance Law §5102(a)(1), office-based surgical centers may recover a facility fee as a reimbursable "basic economic loss," payable at a rate determined in accordance with 11 NYCRR 68.5.

The Court held that because facility fees are not expressly permitted under §5102 and because there are no existing schedules that provide reimbursement for such fees pursuant to §5108, the provider is not entitled to reimbursement under the statute. Noting that the statute expressly permitted hospitals and ambulatory surgery centers ("ASCs") to recoup facility fees under the statute, the Court held that "the absence of such language with regard to [office based surgical] facilities is no mere oversight." The Court also rejected the provider's argument that because the Superintendent has failed to adopt a fee schedule that includes office-based surgery facility fees, those fees are reimbursable under 11 NYCRR 68.5. The Court held that 11 NYCRR 68.5 does not apply, as that provision applies solely to "professional health services." Facility fees, the Court held, do not constitute "services," as they are simply "expenses incurred for services."

The Court likewise rejected the provider's argument that OBS centers should be treated similarly to hospitals and ASCs, which are both entitled to facility fees under the statute. The Court noted that hospitals and ASCs are regulated under Public Health Law Article 28 and are subject to strict standards and DOH regulations governing facility licensing and maintenance; by comparison, OBS facilities are not licensed by the State or regulated by DOH.

The Court also disagreed with the provider's contention that in order to exclude OBS facilities from recouping their facility fees, the Chair and Superintendent must expressly disallow such payments in their fee schedules. The Court held that: (i) there is no statutory duty imposed on the administrators to announce the services and fees they intend to exclude from their schedules; (ii) the administrators may exercise their administrative authority through silence and thereby implicitly reject reimbursement for office-based surgery facility fees; and (iii) it would be unreasonable to construe the No-Fault Law, which was intended to establish a quick and efficient system for obtaining compensation for economic loss as a result of a vehicular accident "in a manner that encourages an even greater level of administrative minutia in the promulgation of what already are mathematically technical, complex fee schedules."

Finally, the Court held that the provider's interpretation of the law undermines the legislative purpose to contain costs by subjecting service charges to statutory ceilings and regulatory fixed rates, and it is up to the legislature and not the court to determine whether the laws should be changed to entitle OBS facilities to facility fees under the no-fault law.

Appellate Division Upholds Department Of Health's "Mask-Wearing Regulation" for Health Care Personnel Who Are Not Vaccinated Against Influenza

Spence v. Shah, No. 136 A.D.3d 1242 (3d Dep't 2016). In 2013, the Department of Health ("DOH") adopted 10 NYCRR 2.59, which requires health care personnel not vaccinated for influenza to wear a surgical or procedural mask during influenza season in areas where patients or residents "may be present." The Public Employees Federation, and four registered nurses represented by that union (collectively "Petitioners"), commenced an article 78 proceeding seeking to annul the regulation on the grounds that the DOH exceeded its authority and acted in an arbitrary, capricious and irrational manner.

The Court first held that the appeal was not moot due to minor amendments to the regulation. The amendments slightly narrowed the mask-wearing requirement from an area where patients "may be present" to where they are "typically present," and carved out a few exceptions, including for personnel who provide speech therapy or work with patients who lip read. The Court ruled that the amendments did not "meaningfully change the mask-wearing requirement for non-vaccinated personnel," and if Petitioners prevailed on appeal, the personnel to whom the current regulation applies will still be affected.

The Court rejected Petitioners' contention that the DOH acted beyond its delegated power and violated the separation of powers doctrine. The Court applied the analysis set forth in *Boreali v. Axelrod*, 71 N.Y.2d 1, 517 N.E.2d 1350 (1987). The four *Boreali* factors include whether the agency: (1) operated outside of its proper sphere of authority by balancing competing social concerns in reliance solely on its own ideas of sound public policy; (2) engaged in typical, interstitial rulemaking or wrote on a clean slate, creating its own comprehensive set of rules without the benefit of legislative guidance; (3) acted in an area in which the Legislature has repeatedly tried, and failed, to reach agreement in the face of substantial public debate and vigorous lobbying by a variety of interested factions; and (4) applied its special expertise or

technical competence to develop the challenged regulations.

The Court reasoned that the DOH's promulgation of the mask-wearing regulation fit within its broad authority, as delegated by the legislature, to implement regulations for the preservation and improvement of public health, and the establishment of standards in health care facilities that serve to foster the prevention and treatment of human disease. The Court explained that the regulation also offered the option of being vaccinated or wearing a mask, which affords workers with options while advancing the tailored goals of minimizing unwarranted public health risk. The Court further noted that although there had been a prior effort by the legislature to address mandatory influenza vaccinations for health care personnel, it had died in committee, and there was no record of repeated efforts to legislatively address the issue. In further justifying the DOH's authority to promulgate 10 NYCRR 2.59, the Court explained that the prevention or reduction of the spread of influenza also implicated scientific and medical issues which are within the DOH's expertise.

The Court also ruled that 10 NYCRR 2.59 was not arbitrary, capricious, irrational and contrary to law. The Court reasoned that the record contained sufficient scientific and factual evidence to support the regulation, including studies and recommendations by the Centers for Disease Control and Prevention, the United States Food and Drug Administration, and the Infectious Disease Society of America.

Appellate Division Upholds Office of Mental Health's "Mask-Wearing Regulation" for Psychiatric Center Personnel Who Are Not Vaccinated Against Influenza

New York State Corr. Officers & Police Benev. Ass'n, Inc. v. New York State Office of Mental Health, 138 A.D.3d 1205 (3d Dep't 2016).

In December 2013, the Office of Mental Health ("OMH") promulgated 14 NYCRR 509.4(c), an emergency regulation that required psychiatric center personnel not vaccinated against influenza wear face masks in areas where patients might be present during influenza season. The petitioner, New York State Correction Officers and Police Benevolent Association, Inc. ("Petitioner"), which represents certain personnel at psychiatric centers operated by OMH, commenced an article 78 proceeding contending that the emergency regulation was arbitrary and capricious. While Petitioner's appeal was pending, OMH codified the emergency regulation into a permanent one. The Supreme Court, Albany County, dismissed the petition and Petitioner appealed.

The Court first ruled that OMH's adoption of a superseding permanent regulation did not moot the appeal, because both regulations would suffer from the same alleged infirmities such that a challenge to the new law would be affected by the resolution of the claims regarding the older law.

The Court rejected Petitioner's argument that psychiatric center treatment personnel's job responsibilities would be hampered by the mask-wearing requirement because it would interfere with their ability to communicate with psychiatric patients. Instead, the Court accepted OMH's position that any disadvantages associated with mask-wearing in psychiatric facilities were outweighed by the substantial advantages they offered in preventing or reducing the transmission of influenza.

In upholding the regulation, the Court relied heavily on an affidavit submitted by Lloyd Sederer, the Chief Medical Officer for OMH. Sederer's affidavit explained that OMH's regulation was simply "following the lead" of a nearly identical regulation promulgated by the Department of Health, and recently upheld by the Third Department. *See Spence v. Shah*, 136 A.D.3d 1242 (3d Dep't 2016) (upholding DOH regulation 10 NYCRR 2.59 which requires that health care personnel who had not been vaccinated for influenza wear a surgical or procedural mask during influenza season in areas where patients or residents "may be present"). The affidavit also addressed Petitioner's concern that the use of masks hampers the ability to communicate, opining that the masks do not significantly impede communication by the slight muffling of sound, because the wearer's eyes, eyebrows, hands and body posture remain visible.

The Court also rejected Petitioner's contention that OMH's regulations were arbitrarily enforced because contractors, attorneys and visitors who enter psychiatric facilities are not required to use masks. In rejecting Petitioner's argument, the Court explained that the regulation requires that contractors wear a mask, and that visitors and attorneys were exempt because they typically spend a limited amount of time in psychiatric facilities and see only one patient at a time, limiting the risk that they transmit influenza.

Second Circuit Holds That Psychiatrists and Their Professional Associations Lack Standing to Bring ERISA Claims on Behalf of Patients

Am. Psychiatric Ass'n v. Anthem Health Plans, Inc., 14 No. Cv. 3993, 2016 WL 2772853 (2d Cir. May 13, 2016).

Two psychiatrists and three professional associations of psychiatrists ("Appellants") brought suit on behalf of their patients and members in the United States District Court for the District of Connecticut against Anthem and its subsidiaries ("Anthem"). The suit alleged that Anthem's reimbursement practices discriminated against patients with mental health and substance use disorders by systemically reimbursing providers of mental health services at a less favorable rate, as compared to coverage for medical and surgical conditions, in violation of the Mental Health Parity and Addiction Equity

Act of 2008 ("MHPAEA") and the Employee Retirement Income Security Act ("ERISA").

Congress enacted MHPAEA to end discrimination in the provision of insurance coverage for mental health and substance use disorder in employer-sponsored group health plans. In short, MHPAEA generally requires that insurers who provide medical benefits and mental health benefits must ensure that the financial requirements and treatment limitations applicable to mental health treatments are no more restrictive than the requirements for medical and surgical benefits. For example, under MHPAEA, insurers are forbidden from having separate treatment limitations that are applicable only with respect to mental health or substance use disorder.

Premised on MHPAEA's anti-discrimination provisions, Appellants argued that Anthem's reimbursement practices violated the anti-discrimination provisions in the MHPAEA and breached Anthem's fiduciary duties under § 502(a)(3) of ERISA. Affirming the District Court's decision, the Second Circuit held that the psychiatrists did not have the authority to assert a cause of action for breach of fiduciary duties under ERISA and that the professional associations lacked constitutional standing to sue on behalf of their members.

At the inception of its decision, the Second Circuit detailed the distinction between constitutional standing, prudential standing, and what was formerly known as "statutory standing." First, the Court explained that constitutional standing refers to the requirement that the parties suing in federal court establish that a "case" or "controversy" exists (requiring an injury in fact, a causal connection between the injury and conduct, and a likelihood that the injury will be redressed by a favorable decision). Second, the Court explained that prudential principles bear on the question of standing and are judicially self-imposed limits on the exercise of federal jurisdiction, which may be altered (for example, one prudential principle is that a plaintiff may ordinarily assert only his own legal rights, but not those of third parties). Finally, the Court noted that the concept of statutory standing was a "misnomer" and that this inquiry is better understood as assessing whether a plaintiff has identified "a cause of action under the statute."

The Court next turned to Appellants' claims, to address each of these three concepts, and the primary issue of whether Appellants can assert a cause of action. The Court found that the psychiatrists had constitutional standing because they would be injured by unfair reimbursement practices. Next, the Court held that because Congress specified in the statute who can bring an ERISA action—"a participant, beneficiary, or fiduciary"—prudential standing principles do not apply. Under *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377, 1387, 188 L. Ed. 2d 392 (2014), the Court is not permitted to expand the Congressionally created statutory list of those who may bring a cause of action by importing third-party prudential standing considerations. Accordingly, because neither the Psychiatrists nor the associations are "participants, beneficiaries, or fiduciaries" under ERISA, they lack a cause of action under ERISA. The Court also held that the associations lacked standing because their members lacked standing.

Second Circuit Holds That Plaintiffs, Acting Through Their Attorneys, Do Not Lack Standing to Assert They Were Overcharged for Copies of Their Medical Records

Carter v. Healthport Technologies, LLC., 2016 WL 2640989 (2d Cir. 2016). Appellants, individually and as representatives of putative classes, allege that Respondents: (i) charged excessive fees for providing copies of their medical records in violation of N.Y. Pub. Health Law §§ 18(2)(d) and (e); and (ii) engaged in deceptive business practices in violation of N.Y. Gen. Bus. Law §§ 349(a) and (h).

Plaintiffs, each of whom had been a patient at a hospital which employed Healthport's services, alleged that the co-defendant hospitals, through Healthport, charged more than the statutory maximum fees permissible under the Public Health Law for providing copies of medical records. Pursuant to N.Y. Pub. Health Law §§ 18(2)(e), a charge must "not exceed… the costs incurred by such provider…." and "the reasonable charge for paper copies shall not exceed seventy-five cents per page." When each of the plaintiffs, through their respective counsel, requested their medical records, Healthport responded that the cost would be 75 cents per page, plus a $2 fee for electronic delivery.

Plaintiffs alleged that the cost to produce the medical records was substantially less than 75 cents per page. Plaintiffs further alleged that by charging excessive fees, failing to disclose the actual cost of producing medical records, and engaging in an undisclosed kickback scheme, Respondents violated the General Business Law's prohibition on deceptive business practices. Defendants moved to dismiss the Complaint under Rule 12(b)(1) for lack of standing, and alternatively under Rule 12(b)(6) for failure to state a claim upon which relief can be granted.

The District Court granted Defendants' motions to dismiss the Complaint under Rule 12(b)(1) on the ground that the allegations were insufficient to establish standing pursuant to Article III. Rendering its decision based solely on the pleadings, the Court held that the Complaint failed to establish that Plaintiffs, rather than their counsel, requested or paid for the copies of their medical records. The District Court did not address Defendants' motions to dismiss under Rule 12(b)(6).

The Court of Appeals reversed, holding that due to the agent-principal relationship between an attorney and client, the Complaint had indeed alleged that Plaintiffs, acting through their agent-attorneys, were

the ultimate requestors and payors. Specifically, the Court held that the attorneys' statements in their letters requesting the medical records that they would "promptly reimburse you" did not suggest that their clients were not the ultimate payors. Accordingly, the Court concluded that, based upon the allegations of the Complaint, Plaintiffs themselves had suffered the requisite injury in fact to establish standing.

The Court's analysis also addressed the traceability from Healthport to the hospitals, holding that a plaintiff's injury need not be directly attributable to the defendant in order to show causation for purposes of standing, so long as the injury is "fairly traceable." In so holding, the Court rejected as "border[ing] on the frivolous" the hospitals' argument that they themselves did not directly overcharge Plaintiffs, and held that any response to a request for medical records on behalf of a health care provider is "fairly traceable" to that provider.

Second Circuit Finds That Pharmaceutical Company Did Not Violate the False Claims Act by Marketing Drug to Patients Beyond Guidelines Referenced in the Label

United States ex rel. Polansky v. Pfizer, Inc., 2016 WL 2865610 (2d Cir. May 17, 2016). Relator is a former employee of Defendant Pfizer, Inc. ("Pfizer"), a pharmaceutical company that manufactures and markets Lipitor, a popular statin. Relator brought claims against Pfizer under the False Claims Act (the "FCA") and related state law claims, alleging that the company improperly marketed Lipitor to patients that did not meet the risk factors and cholesterol levels recommended by the National Cholesterol Education Program Guidelines (the "Guidelines"), that compliance with the Guidelines was mandated by the Food and Drug Administration (the "FDA") because they were referenced in Lipitor's label, and that Pfizer caused federal and state health care programs to pay for "off-label" prescriptions.

Under the Food, Drug and Cosmetic Act, pharmaceutical companies must obtain FDA approval before marketing or selling any drug for any intended use. The drug's label, which contains information on its indications, contra-indications, limitations of use, use by specific populations, and dosage instructions, among other things, must also be approved by the FDA. Although physicians are entitled to prescribe an FDA-approved drug for any "on-label" or "off-label" use, Pharmaceutical companies are generally prohibited from marketing a drug for any off-label use. Significantly, federal and state health care programs—including Medicare and Medicaid—generally provide reimbursement only for drugs that are prescribed for on-label uses.

During the relevant time period, Lipitor was FDA-approved for five separate indications relating to the treatment of elevated cholesterol. From 2001 until 2009, Lipitor's label contained two parenthetical references to the Guidelines, as well as a table summarizing the Guidelines' recommendations. In 2009, Pfizer removed the table and one of the two parenthetical references. The parties agreed that despite this modification, the post-2009 label was substantively identical to the pre-2009 label.

Relator filed suit in the United States District Court for the Eastern District of New York. He claimed that the Guidelines were incorporated by reference into Lipitor's label, and thus the drug was only approved for use with patients whose risk factors and cholesterol levels fell within the framework set forth therein. Relator alleged that Pfizer marketed Lipitor broadly to patients that fell outside of the Guidelines, thus causing prescriptions to be written and filled for off-label uses. Relator argued that when Pfizer sought reimbursement for these prescriptions, it impliedly and falsely certified that the prescription was for an on-label use.

The district court dismissed the FCA and related state law claims in Relator's initial complaint, finding that they were not pled with particularity as required by Federal Rule of Civil Procedure 9(b). When Relator then amended his claims, they were once again dismissed by district court, this time upon a finding that the label did not require compliance with the Guidelines. Relator appealed this second ruling by certification.

The Second Circuit affirmed the district court's holding. It asserted that the Guidelines merely provide advice, not binding limitations on the drug's use. The court found it dispositive that the Guidelines themselves expressly indicated that they provide "general guidance" and that they are not to override a physician's medical judgment with respect to any individual patient. As the Guidelines were "clearly intended to be advisory guidance," the Second Circuit agreed with the district court that they could not be "transformed into a legal restriction simply because the FDA has determined to pass along that that advice through the label."

The court also noted that the label imposed certain restrictions for pediatric patients, but no similar restriction for adults. The court found that this "express restriction… shows how easily the FDA could have mandated compliance with the NCEP Guidelines with respect to all patients if it wanted to do so." The court then held that this conclusion is "reinforced" by the fact that Pfizer removed nearly all references to the Guidelines in 2009 without making any substantive changes to the label.

Finally, in dicta, the court expressed skepticism of Relator's contention that any false claim had been made. The court stated that doctors are entitled to prescribe Lipitor for off-label uses, patients are most likely not aware when the use is off-label, and the prescription does not indicate to the pharmacy whether the use is on- or off-label. The court inferred that perhaps Relator's theory

of liability could apply where drugs are marketed for "purpose[s] obviously not contemplated by the label," but not when they are marketed to certain populations that are "neither specified nor excluded from the label."

Court Denies District Attorney's Motion to Speak With Defendant's Psychiatric Physicians in Advance of Hearing to Determine Whether Defendant Is Dangerously Mentally Ill

Miccoli v. W.T., 2016 WL 1757635 (Sup. Ct. New York Cty., Apr. 28, 2016). The Nassau District Attorney's Office ("DA") sought an order authorizing the doctors and staff of Kirby Forensic Psychiatric Center (the "Hospital") to speak with the DA concerning the treatment and care of Defendant. The DA sought this order to prepare for a hearing, pursuant to CPL § 330.20(8) to determine whether Defendant is dangerously mentally ill and should be retained at the Hospital. Defendant had spent 31 years in the custody of New York State Commissioner of Mental Health, following determination in 1982 of his non-responsibility for a murder charge by reason of mental disease.

In 2013 the patient was released with an order of conditions, which, among other things, included scheduled appointments for injectable medications. In January of 2014 Defendant missed a scheduled appointment and was recommitted. The Commissioner submitted a first order of retention and Defendant's attorney, Mental Hygiene Legal Services ("MHLS"), requested a hearing pursuant to CPL § 330.20.

The DA moved for an order directing the Hospital to give the DA access to the Defendant's medical records. Defendant did not object and thus the medical records were provided to the DA. The DA also requested permission to speak with the doctors and staff members who made entries in the medical records. MHLS objected to the DA speaking with the doctors and staff of the Hospital.

The DA argued that Defendant waived any privileges as to his mental status by putting his mental state at issue when he requested a hearing pursuant to CPL § 330.20, and also waived any privilege by pleading insanity in 1982. The Court first held that the 1982 plea in a criminal case did not constitute a waiver in the CPL § 330.20(8) hearing, which is a separate civil proceeding. Thus, any waiver in the original criminal proceeding did not apply to future civil commitment proceedings. The court also held that a person whom the Commissioner seeks to retain in a psychiatric hospital does not put his mental health at issue merely by demanding a hearing.

The DA also argued that the disclosure is warranted because the Defendant was given notice of the request for the records in accordance with federal privacy rules. 45 CFR 164.512(e)(1)(i),(ii) of the federal privacy rules allows disclosure by a court order or subpoena; however, the court noted that this is a floor, not a ceiling. Instead, the DA had to the meet the more burdensome requirements of MHL § 33.13(c)(1), which allows disclosure only "upon a finding by the court that the interests of justice significantly outweigh the need for confidentiality." Here, the DA did not even allege that the interests of justice significantly outweigh the needs for confidentiality. Similarly, the court held that the DA did not establish the necessity for the disclosure requested. The court also noted that the DA did not request an independent psychiatric examination by a non-treating examiner who could have testified.

Nevertheless, the court did state that if upon review of the records and the independent examiner's potential testimony, the DA still believes that it cannot meet its burden in the proceeding, an application may be made to the Court outlining the specific need to speak with the Defendant's treating doctors and staff.

Compiled by Leonard Rosenberg, Esq. Mr. Rosenberg is a shareholder in the firm of Garfunkel Wild, P.C., a full service health care firm representing hospitals, health care systems, physician group practices, individual practitioners, nursing homes and other health-related businesses and organizations. Mr. Rosenberg is Chair of the firm's litigation group, and his practice includes advising clients concerning general health care law issues and litigation, including medical staff and peer review issues, employment law, disability discrimination, defamation, contract, administrative and regulatory issues, professional discipline, and directors' and officers' liability claims.

In the New York State Legislature

By James W. Lytle

End of Session, 2016

As of this writing, the 2016 Legislative session has just come to a close and a range of health care issues were addressed in the closing weeks, days and hours of the session, which may be of interest to the health law practitioner. A preliminary (and somewhat arbitrary) summary of some of the bills that have passed both houses—most of which have not yet been signed by the Governor—follows:

Opioid Epidemic

The heroin and opioid health crisis has, for the second time in three years, spawned a package of bills, which were undertaken at the Governor's request:

A.10726 (Cusick)/S.8138 (Amedore). Requires hospitals to have discharge materials for people who have or appear to have a substance abuse disorder and develop policies on identification, assessment, and referral for patients with a documented substance abuse disorder. Protects health care professionals from professional misconduct charges if administer an opioid antagonist in an emergency.

A.10725 (Steck)/S.8137 (Ortt). Requires insurers to provide immediate access, without prior authorization, to a five day supply of those medications used to treat substance use disorders, including those associated with the management of opioid withdrawal and/or stabilization, in emergency situations. Prohibits prior authorization by Medicaid managed care organizations and the fee-for-service program for buprenorphine or injectable naltrexone for the purposes of treating opioid addiction, unless the prescription is for a non-preferred or non-formulary form of the drug. Extends the time persons suffering from addiction can be held

without their consent from 48 to 72 hours, if the provider believes they may present a threat to themselves or others. Requires that utilization review of substance abuse disorders are undertaken in accordance with approved tools. Also authorizes wraparound services demonstration program to include inpatient and outpatient treatment.

A.10727 (Rosenthal)/S.8139 (Murphy). Exempts the first 14 days of inpatient treatment for substance use disorders from prior approval or concurrent utilization review by health insurers when the treatment is provided by an Office of Alcohol and Substance Abuse ("OASAS") certified facility that is participating in the insurer's provider network. Requires that the facility providing treatment conduct a daily clinical assessment of the patient, using an "evidence-based and peer reviewed clinical review tool" designated by OASAS and selected by the insurer, and engage in periodic consultation with the insurer to ensure that such an assessment is being completed. Prohibits the facility from holding the patient financially responsible for these services, other than in the case of copays, coinsurance and deductibles. Still permits insurers to engage in utilization review of a patient's first 14 days of inpatient treatment, after it has been completed, for which it may deny coverage if the services are not medical necessary, provided that it utilizes the above-referenced tool and allows an insurer to engage in concurrent utilization review of the remainder of a patient's inpatient treatment.

Also limits initial prescriptions for opioids to a seven day supply for those patients that are being treated for acute pain, where the practitioner reasonably expects the condition will last only a short period of time, and does not include chronic pain, pain associated with cancer care, hospice or end-of-life care, or pain treated as part of palliative care services.

Prohibits insurers from charging patients a higher copay as a result of this more limited initial prescription by requiring that the copay be proportional to that copay charged for a 30-day supply or equal to the copay for the 30-day supply, provided no additional copay is required if the patient fills the a prescription for the remaining 30 days. Requires medical residents and all health professionals licensed under title eight of the education law who are DEA registered to undergo course work or training in pain management, palliative care and addiction.

Authorizes pharmacies to distribute informational materials to persons receiving controlled substances and to provide counseling and referral services (relating to Hepatitis C, HIV, drug overdose risks and other issues) to persons purchasing hypodermic syringes.

Step Therapy

A.2384-D (Titone)/S.3419-C (Young). Requires insurers to provide clinical review criteria relating to step therapy protocol override determinations to health care professionals. Defines step therapy protocols to include policies that establish a sequence in which prescription drugs may be approved and allows those determinations to be overridden within 72 hours where the health care professional has documented potential adverse reaction, has demonstrated that the step therapy protocol recommended drug will be ineffective, or has shown other

compelling circumstances justifying overriding the protocol.

Organ Donation

The persistently poor performance of the New York State organ donor registry, coupled with a growing waiting list for prospective transplant recipients, helped spur legislative action on this front.

Young Organ Donors, A.4990-B (Ortiz)/S.5313-A (Hannon). Allows persons 16 and older to register as organ donors. Specifies that parents would retain the right to rescind the potential donor's consent if, at the time of donation, the donor was not yet eighteen. *Passed both houses.*

Registration Through Exchange, A.9667-A (Gunther)/S.6952-A/chapter 40 of the laws of 2016 (Hannon). Requires New York State of Health insurance exchange to provide for the opportunity for individuals to register as organ donors.

Lauren's Law Extension, A.8594 (Ortiz)/S.6228 (Carlucci). Extends recently enhanced Lauren's Law, which requires driver's license applicants to be asked if they would like to become organ donors. Currently scheduled to expire in October 2016, the bill would extend these provisions for an additional four years.

Breast Cancer Prevention

A.10679 (Barrett)/S.8093 (Flanagan). Requires mammography providers to offer at least four hours of breast cancer screenings outside of normal business hours per week to enhance access to these services, consistent with recently issued regulations. Prohibits deductibles and coinsurance for the screenings.

Professional licensing

Pathologists' Assistant Licensure, A.10408 (Harris)/S.7932 (LaValle). Creates a new licensure category for pathologists' assistants, who perform gross tissue examination and dissection, select specimens to serve as the basis for pathologist diagnoses, and help perform autopsies. Establishes a process that enables experienced individuals who may not meet all of the proposed education and examination requirements to be licensed, provided their supervising pathologists attest to their experience and competence.

Advanced Home Health Aides, A.10707 (Glick)/S.8110 (LaValle). Authorizes expanded roles for home health aides, subject to regulations adopted by the Commissioner of Education, in consultation with the Commissioner of Health. The regulations will define the advanced tasks that may be performed, the appropriate supervision and delegation requirements, and the training, experience and certification requirements that will govern these advanced home health aides.

Hospital Finance

Safety Net Hospitals, A.9476-A (Gottfried)/S.6948-A (Hannon). Requires the DOH Commissioner to establish a supplemental Medicaid rate adjustment for "enhanced safety net hospitals" that:

- Are public, critical access, and sole community hospitals that provide emergency room, hospital based- and community-based clinics that provide dental and prenatal care and other important community services;
- Serve patient populations that are at least fifty percent Medicaid or uninsured and that have at least 40% Medicaid inpatient discharges;
- Have no more than 25 percent commercially insured patients and at least three percent uninsured.

The amount of the adjustment is at the discretion of the commissioner. The funding for the enhancement is not set forth in the legislation and would be subject to budgetary appropriation. For that reason, the bill does not take effect until April 1 of next year, coincident with the commencement of the next fiscal year.

Kings County Health Care Transparency, A.9515 (Brennan)/S.7112 (Golden). Requires greater transparency governing this initiative, which involves the investment of $700 million in capital support to improve health care in Brooklyn, by mandating the Department of Health and Dormitory Authority of the State of New York to release program applications and to hold at least one public hearing in Brooklyn at least 60 days before making awards.

Unclaimed Cadavers

A.6372-D (Simanowitz)/S.4430-D (Felder) Requires educational institutions in New York City, including medical and mortuary schools, to attempt to locate the next of kin for unclaimed bodies prior to their release, a responsibility that currently resides with the New York City Office of the Chief Medical Examiner. Removes the authority of a public administrator or county chief fiscal officer to consent to release an unclaimed body for the purposes of medical education.

New Hospital Mandates

Human Trafficking Victims, A.8650-B (Paulin)/S.6835-B (Lanza). Requires hospitals and other health care facilities to establish and implement policies and procedures for identifying, assessing, and treating or referring persons suspected as victims of human trafficking. The bill would also require personnel in these facilities to complete training on these policies.

Safe Sleep, A.7181/S.5100 (Paulin/Lanza). Requires DOH's maternity information leaflet, which health care providers give to new mothers, to contain information about infant safe sleep practices. The legislation also provides that the information may be offered in the form of a video.

Out-of-Network Law/Caregiver Law, A.9188-B(Gunther)/S.6347-B (Hannon). Requires the hospital patient bill of rights to state that a list of standard charges and participating health plans is available on the hospital website, that patients have a right to be held harmless from surprise

bills and emergency services bills, and that they have a right to designate a caregiver under the Caregiver Advise, Record, and Enable (CARE) Act.

HIV Confidentiality

A.9834 (Gottfried)/S.7505 (Hannon). Broadens the New York State HIV confidentiality law to allow for disclosure of HIV information without patient authorization for research purposes, where approved by an institutional review board.

Off-Site Services

Outpatient Services in Offsite Locations, A.7714-C/S.8081 (Gottfried/Hannon). Allows hospitals to provide outpatient clinic services in offsite locations to chronically ill patients who are permanently or temporarily homebound, including patients who reside in long term-care settings.

Clarification of Non-Profit Revitalization Act

A.10365-B(Brennan)/S.7913-B (Ranzenhofer). Amends certain provisions of the Not-for-Profit Corporation Law that were amended by the Non-Profit Revitalization Act of 2013 (NPRA) to clarify terms and requirements pertaining to "independent directors" and "key persons," "related party transactions," "conflicts of interest" and other provisions in order to streamline and conform these provisions.

Midwifery Birth Centers

Midwifery Birth Centers, A.446/S.4325 (Gottfried/Hannon). Would authorize midwifery birth centers that are supervised by midwives and directs the DOH Commissioner to promulgate regulations for these centers.

Mental Health Education

A.3887-B (Nolan)/S.6046-A(Marcellino). Mandates that school health education programs recognize and include mental health issues to "enhance student understanding, attitudes and behaviors that promote health, well-being and human dignity."

OPWDD Transformation Panel

A.10053-A (Gunther)/S.7644-A (Ortt). Mandates quarterly reports from OPWDD on the progress made in implementing recommendations made by the OPWDD Transformation Panel, including any statutory or regulatory obstacles to implementation.

Jim Lytle is a partner in the Albany office of Manatt, Phelps & Phillips, LLP.

In the New York State Agencies

by Francis J. Serbaroli

Standards for Individual Onsite Water Supply and Individual Onsite Wastewater Treatment Systems

Notice of Adoption. The Department of Health amended Part 75 of Title 10 NYCRR to establish minimum water quality standards for individual onsite water supply systems. Filing date: March 1, 2016. Effective date: March 16, 2016. *See* N.Y. Register March 16, 2016.

General Provisions Concerning State Aid Eligibility

Notice of Adoption. The Department of Health amended section 40-2.1 of Title 10 NYCRR to clarify that rent and maintenance of space in lieu of rent (MILOR) remain eligible for State Aid. Filing date: March 1, 2016. Effective date: March 16, 2016. *See* N.Y. Register March 16, 2016.

Conforming Changes Related to Chapter 106 of the Laws of 2015

Notice of Emergency/Proposed Rulemaking. The Office for People With Developmental Disabilities amended section 633.21 of Title 14 NYCRR to make changes to regulations to conform to recent statutory changes set forth in chapter 106 of the Laws of 2015. Filing date: March 1, 2016. Effective date: March 1, 2016. *See* N.Y. Register March 16, 2016.

Article 16 Clinic Services and Independent Practitioner Services for Individuals with Developmental Disabilities (IPSIDD)

Notice of Adoption. The Office for People With Developmental Disabilities amended Part 679, sections 635-10.4, 671.5; and added Subpart 635-13 to Title 14 NYCRR to discontinue off-site article 16 clinic services and add requirements for IPSIDD. Filing date: March 11, 2016. Effective date: April 1, 2016. *See* N.Y. Register March 30, 2016.

Zika Action Plan; Performance Standards

Notice of Emergency Rulemaking. The Department of Health added section 40-2.24 to Title 10 NYCRR to require local health departments to develop a Zika Action Plan as a condition of State Aid. Filing date: March 17, 2016. Effective date: March 17, 2016. *See* N.Y. Register April 6, 2016.

Rate Rationalization—Prevocational Services, Respite, Supported Employment and Residential Habilitation

Notice of Adoption. The Department of Health added Subpart 86-13 to Title 10 NYCRR to establish new rate methodology effective July 1, 2015. Filing date: March 25, 2016. Effective date: April 13, 2016. *See* N.Y. Register April 13, 2016.

Medicaid Provider Enrollment

Notice of Adoption. The Department of Health amended section 504.5 of Title 18 NYCRR to make technical, conforming changes to regulations governing the enrollment of Medicaid providers of care, services and supplies. Filing date: March 25, 2016. Effective date: April 13, 2016. *See* N.Y. Register April 13, 2016.

Zika Action Plan; Performance Standards

Notice of Proposed Rulemaking. The Department of Health proposed adding section 40-2.24 to Title 10 NYCRR to require local health departments to develop a Zika Action Plan as a condition of State Aid. *See* N.Y. Register April 13, 2016.

Zika Action Plan; Performance Standards

Regulatory Impact Statement. The Department of Health issued a Regulatory Impact Statement related to the Zika Action Plan and Performance Standards made through an emergency rulemaking published in the April 6, 2016 issue of the N.Y. Register. *See* N.Y. Register April 13, 2016.

Site-Based Prevocational Services Certification and Physical Plant Requirements

Notice of Proposed Rulemaking. The Office for People With Developmental Disabilities proposed amending section 635-7.5 of Title 14 NYCRR to apply existing physical plant and certification requirements in OPWDD regulations to site-based prevocational services. *See* N.Y. Register April 13, 2016.

Medical Indemnity Fund

Notice of Proposed Rulemaking. The Department of Health proposed amending Subpart 69-10 of Title 10 NYCRR to provide additional guidance and clarity to the Fund's requirements and operations. *See* N.Y. Register April 20, 2016.

Protection Against Legionella

Notice of Proposed Rulemaking. The Department of Health proposed adding Part 4 to Title 10 NYCRR to protect the public from the immediate threat posed by Legionella. *See* N.Y. Register April 20, 2016.

Article 16 Clinic Services and Independent Practitioner Services for Individuals with Developmental Disabilities (IPSIDD)

Amended Notice of Adoption. The Office for People With Developmental Disabilities amended Parts 635, 671 and 679; and added Subpart

635-13 to Title 14 NYCRR to discontinue off-site article 16 clinic services and add requirements for IPSIDD. Filing date: March 30, 2016. Effective date: April 20, 2016. *See* N.Y. Register April 20, 2016.

Cost Report Submission and Penalty Changes

Notice of Proposed Rulemaking. The Office for People With Developmental Disabilities proposed amending section 635-4.4 of Title 14 NYCRR to amend requirements for submission of cost reports and penalties for failure to submit cost reports to OPWDD. *See* N.Y. Register April 20, 2016.

Transgender-Related Care and Services

Notice of Adoption. The Department of Health amended section 505.2(l) of Title 18 NYCRR to amend provisions regarding Medicaid coverage of transition-related transgender care and services. Filing date: April 12, 2016. Effective date: April 27, 2016. *See* N.Y. Register April 27, 2016.

Rights of Patients

Notice of Adoption. The Office of Mental Health amended section 527.8 of Title 14 NYCRR to make clear that conversion therapy is not a permissible form of treatment for minors in facilities under OMH's jurisdiction. Filing date: April 12, 2016. Effective date: April 27, 2016. *See* N.Y. Register April 27, 2016.

Telepsychiatry Services

Notice of Proposed Rulemaking. The Office of Mental Health proposed adding Part 596 and repealing section 599.17 of Title 14 NYCRR, to establish basic standards to approve telepsychiatry in certain OMH-licensed programs; repeal unnecessary existing provisions. *See* N.Y. Register April 27, 2016.

Home Care Agencies to Obtain Written Medical Orders from Physicians

Notice of Adoption. The Department of Health amended sections 763.7 and 766.4 of Title 10 NYCRR to amend the clinical records rules for CHHAs and LHCSAs with regard to obtaining signed physician orders. Filing date: April 19, 2016. Effective date: May 4, 2016. *See* N.Y. Register May 4, 2016.

Incident Management, Criminal History Record Checks, Operation of Psychiatric Inpatient Units, General Hospitals, RTFs, and CPEPs

Notice of Proposed Rulemaking. The Office of Mental Health proposed amending Parts 524, 550, 580, 584 and 590 of Title 14 NYCRR to update existing regulations and conform to non-discretionary statutory provisions. *See* N.Y. Register May 4, 2016.

Transgender-Related Care and Services

Notice Proposed Rulemaking. The Office of Mental Health proposed amending section 505.2(l) of Title 18 NYCRR to revise and clarify the criteria for Medicaid coverage of transgender-related care and services. *See* N.Y. Register May 11, 2016.

OASAS Treatment Services: General Provisions

Notice of Proposed Rulemaking. The Office of Alcoholism and Substance Abuse Services proposed amending Part 800 of Title 14 NYCRR to include all mental health practitioners as qualified health professionals (QHP). *See* N.Y. Register May 18, 2016.

General Facility Requirements

Notice of Proposed Rulemaking. The Office of Alcoholism and Substance Abuse Services proposed repealing Part 814 and adding a new Part 814 to Title 14 NYCRR to update provisions applicable to all certified facilities due to: residential redesign, changes in certification and inspections. *See* N.Y. Register May 18, 2016.

Incident Reporting in OASAS Certified, Licensed, Funded, or Operated Services

Notice of Proposed Rulemaking. The Office of Alcoholism and Substance Abuse Services proposed amending Part 836 of Title 14 NYCRR to clarify requirements for reporting patient deaths. *See* N.Y. Register May 18, 2016.

Sexually Transmitted Diseases (STDs)

Notice of Adoption. The Department of Health amended Part 23 of Title 10 NYCRR to add provisions to control of Sexually Transmitted Diseases (STDs); Expedited Partner Therapy for Chlamydia Trachomatis Infection. Filing date: May 3, 2016. Effective date: May 18, 2016. *See* N.Y. Register May 18, 2016.

Extended Mammography Hours for General Hospitals and Hospital Extension Clinics

Notice of Adoption. The Department of Health added section 405.33 to Title 10 NYCRR to require those general hospitals and hospital extension clinics that offer mammography services to have extended hours. Filing date: May 3, 2016. Effective date: May 18, 2016. *See* N.Y. Register May 18, 2016.

Supplementary Reports of Certain Birth Defects for Epidemiological Surveillance; Filing

Notice of Adoption. The Department of Health amended sections 22.3 and 22.9 of Title 10 NYCRR to increase the maximum age of reporting certain birth defects to the Birth Defect Registry. Filing date: May 4, 2016. Effective date: May 25, 2016. *See* N.Y. Register May 25, 2016.

Immediate Need for Personal Care Services (PCS) and Consumer-Directed Personal Assistance (CDPA)

Notice of Adoption. The Department of Health amended sections 505.14 and 505.28 of Title 18 NYCRR to implement 2015 State law changes regarding Medicaid applicants and recipients with immediate needs for PCS or CDPA. Filing date: May 5, 2016. Effective date: June 7, 2016. *See* N.Y. Register May 25, 2016.

New York State Newborn Screening Panel

Notice of Proposed Rulemaking. The Department of Health proposed amending section 69-1.2 of Title 10 NYCRR to add adrenoleukodystrophy (ALD) and Pompe disease to the list of diseases and conditions on the newborn screening panel. *See* N.Y. Register May 25, 2016.

Protection Against Legionella

Notice of Emergency Rulemaking. The Department of Health added Part 4 to Title 10 NYCRR to protect the public from the immediate threat posed by Legionella. Filing date: May 11, 2016. Effective date: May 11, 2016. *See* N.Y. Register June 1, 2016.

Directors of Mental Hygiene Facilities as Representative Payees

Notice of Adoption. The Office of Mental Health added Part 522 to Title 14 NYCRR to implement provisions of Mental Hygiene Law section 33.07(e) regarding the management and protection of patient funds. Filing date: May 12, 2016. Effective date: June 1, 2016. *See* N.Y. Register June 1, 2016.

Changes to the Pathway to Employment Service

Notice of Adoption. The Office for People With Developmental Disabilities amended Subpart 635-10 of Title 14 NYCRR to make changes to requirements for the delivery and reimbursement of the Pathway to Employment service. Filing date: May 17, 2016. Effective date: June 1, 2016. *See* N.Y. Register June 1, 2016.

School Immunization Requirements

Notice of Proposed Rulemaking. The Department of Health proposed amending Subpart 66-1 of Title 10 NYCRR to update school immunization and NYSIIS regulations. *See* N.Y. Register June 8, 2016.

Neurodegenerative Specialty Rate

Notice of Proposed Rulemaking. The Department of Health proposed amending Subpart 86-2 of Title 10 NYCRR to authorize Medicaid rate of payment for providing quality of care to the neurodegenerative population. *See* N.Y. Register June 15, 2016.

Specialized Programs for Residents with Neurodegenerative Diseases

Notice of Proposed Rulemaking. The Department of Health proposed adding section 415.41 to Title 10 NYCRR to establish nursing home specialty units for residents with Huntington's Disease (HD) and Amyotrophic Lateral Sclerosis (ALS). *See* N.Y. Register June 15, 2016.

Compiled by Francis J. Serbaroli. Mr. Serbaroli is a shareholder in the Health & FDA Business Group of Greenberg Traurig's New York office. He is the former Vice Chairman of the New York State Public Health Council, writes the "Health Law" column for the *New York Law Journal*, and is the former Chair of the Health Law Section. The assistance of Caroline B. Brancatella, an associate of Greenberg Traurig's Health and FDA Business Group, in compiling this summary is gratefully acknowledged.

New York State Fraud, Abuse And Compliance Developments

Edited By Melissa M. Zambri

New York State Department of Health OMIG Audit Decisions

Compiled by Margaret Surowka Rossi

Andrew L. Satran, M.D. (DOH administrative hearing decision dated March 12, 2015, Denise Lepicier, Administrative Law Judge). The Appellant requested a hearing from a Final Audit Report dated April 8, 2014 and the hearing was originally set for August 6, 2014. The hearing was adjourned a number of times and was finally set for hearing on February 10, 2015. The Department appeared but the Appellant failed to appear and did not request an adjournment. As such, the administrative proceeding was deemed abandoned.

Rachel Liyun Sun, DMD (DOH administrative hearing decision dated March 30, 2016, David A. Lenihan, Administrative Law Judge). This was a review of a determination by the Department, excluding the provider dentist for a period of three years and to recover $24,945.00 in Medicaid overpayments. A Notice of Agency Action ("NOAA") dated July 30, 2015 was sent to the Appellant notifying her of the exclusion and restitution amount sought by OMIG. The NOAA provided that Appellant had 60 days to request a hearing. Appellant requested a hearing by letter dated October 14, 2015. Appellant had been out of the country and did not receive the NOAA until the end of September. The ALJ held that the primary issue was that of notice and the 60-day time frame fixed by the Social Services Law *runs from the time of actual notice*. Since the Appellant did not receive the notice until the end of September, the ALJ found that her request for a hearing was timely and the Appellant should be granted a hearing.

Long Island Medical Associates (DOH administrative hearing decision dated March 22, 2016, Kimberly A. O'Brien, Administrative Law Judge). This was an appeal from a September 10, 2009 Final Medicaid Audit Reimbursement Report for the rate period January 1, 1999 through December 31, 2004 for a licensed diagnostic and treatment center. The Department adjusted and/or disallowed Appellant's operating expenses for prior year startup costs and four categories of capital expense disallowances, including auto lease expense, amortization expenses, prior period rental expense, and related party rental expense totaling overpayments in the amount of $931,442.00. The ALJ reviewed each category of disallowance and found that Appellant failed to show that the disallowed expenses should be allowed.

Riverhead Care Center, Inc. (DOH administrative hearing decision dated March 15, 2016, Ann H. Gayle, Administrative Law Judge). This was an audit of a residential health care facility's ("RHCF") costs for the period January 1, 2005 through December 31, 2008. OMIG's Final Audit Report determined a Medicaid overpayment in the amount of $175,550. The only issue for hearing was the disallowance of property item number 2, Interest Expenses for the year 2005 and 2006. The interest was on a property improvement loan which was utilized for a renovation. Appellant argued that DOH approved the renovation project, including the cost and financing of the project, and thereby implicitly allowed reimbursement for the interest associated with that financing. OMIG argued that Appellant's "excessive equity withdrawals" necessitated the borrowing of the funds for which it sought the interest payment expense. The OMIG auditors' review of the Appellant's financial records showed that the owners had withdrawn $4.57 million of equity in the 3-4 years prior to the loan period and they argued that there would have been no need for the loan had those withdrawals not occurred. The ALJ agreed stating: "Obtaining a loan, at Medicaid expense, to finance a patient care-related renovation project might make good financial and accounting sense for the owners and the business, but the Medicaid Program should not pay those costs as it will not reimburse a provider for the cost of unnecessary borrowing." Therefore, the ALJ affirmed the disallowance of the loan interest and upheld the overpayments.

Allcare Transportation Inc. (DOH administrative hearing decision dated April 15, 2016, David A. Lenihan, Administrative Law Judge). This hearing was to review a determination by OMIG to recover alleged overpayments made to a transportation provider in the amount of $4,675.92, inclusive of interest. The Appellant requested a hearing by letter dated March 25, 2013 and after several adjournments, a hearing was scheduled for April 12, 2016. The hearing was adjourned several times and was set for hearing on February 10, 2015. The Department appeared but the Appellant failed to appear and did not request an adjournment. As such, the administrative proceeding was deemed abandoned.

New York State Attorney General Press Releases

Compiled by Joseph A. Murphy and Eric W. Dyer

Nurse Aide Arrested for Allegedly Slapping Nursing Home Resident—June 14, 2016—A nurse aide at a Buffalo nursing home was arrested

for allegedly slapping an 88-year-old resident on the head and face. The resident had Alzheimer's disease and acute kidney failure and was incapable of caring for himself. The nurse aide has pleaded not guilty to charges of endangering the welfare of an incompetent or physically disabled person in the second degree, wilful violation of health laws, and harassment in the second degree. http://www.ag.ny.gov/press-release/ag-schnei derman-announces-arrest-nurse-aide-allegedly-slapping-nursing-home-resident.

Three Women Arrested for Conspiring to Defraud Medicaid by Billing over $13,600 in Services Not Provided to a Family Member with Cerebral Palsy—June 9, 2016—A mother, daughter and family friend were arrested for allegedly submitting false timesheets for care they did not provide to another family member who suffers from Cerebral Palsy. The three then billed Medicaid for $13,661.50. The charges against the three include grand larceny in the third degree, health care fraud in the fourth degree and offering a false instrument for filing in the first degree. The women face up to seven years in prison. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-3-women-who-allegedly-conspired-defraud-medicaid.

Two Nurses Indicted and Arraigned for Allegedly Neglecting a Severely Disabled Resident—June 2, 2016—Two nurses at a Queens nursing home were indicted and arraigned for allegedly neglecting to treat a disabled resident suffering from a head injury for over twenty minutes. Both nurses allegedly ignored the resident and failed to provide care despite the resident crawling on the floor with blood coming from his head and jaw. Both nurses were charged with endangering the welfare of an incompetent or physically disabled person in the first degree and wilful violation of health laws, and one was also charged with falsifying business records in the first degree for allegedly attempting to conceal the incident. http://www.ag.ny.gov/press-release/ag-schnei derman-announces-indictment-and-arraignment-two-nurses-allegedly-neglecting.

Pharmacy Settles Charges That It Billed Medicaid for 4,600 Prescriptions Written by an Excluded Provider—May 26, 2016—The Attorney General has reached an agreement with a pharmacy over allegations that the pharmacy billed Medicaid for prescriptions from an excluded Medicaid provider. Between April 2010 and January 2013, the pharmacy billed 4,600 claims to Medicaid for prescriptions that were written by an excluded doctor. The settlement requires the pharmacy to pay New York $422,000, plus $36,000 in damages under the New York False Claims Act. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-pharmacy-billed-medicaid-4600-prescriptions.

Attorney General Announces Elder Investment Fraud and Financial Exploitation Prevention Program—May 26, 2016—The Attorney General launched the Elder Investment Fraud and Financial Exploitation (EIFFE) Prevention Program in New York. The Investor Protection Bureau will help medical professionals understand elder investment fraud through Continuing Medical Education training sessions. The program aims to educate medical professionals on preventing, detecting, and reporting investment fraud involving elderly patients. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-launch-elder-investment-fraud-and-financial-exploitation.

Three-Quarter Housing Operators Indicted on Charges of Medicaid Fraud and Money Laundering—May 18, 2016—Two "three-quarter house" operators in New York City, along with their corporate entities, were indicted and arraigned for an alleged kickback scheme with a Medicaid-enrolled drug treatment provider. The operators allegedly received over $600,000 in illegal kickbacks through various corporations they controlled. They were charged with grand larceny in the second degree, money laundering in the second degree, and violations of the Social Services Law prohibiting the payment of kickbacks related to the provision of services under the State's Medicaid program. The charges carry a maximum term of fifteen years of incarceration. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-indictment-and-arraignment-three-quarter-housing-operators.

Certified Nurse Aide Sentenced to Prison for Fracturing Resident's Elbow—May 12, 2016—A Syracuse certified nurse aide pleaded guilty to endangering the welfare of a vulnerable elderly person or an incompetent or physically disabled person in the second degree after being secretly videotaped striking a 92-year old nursing home resident, causing the resident to suffer an elbow fracture. The aide was sentenced to six months in prison and five years' probation. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-prison-time-nursing-home-aide-who-fractured-resident%E2%80%99s-elbow.

New York Offers Assistance for Individuals and Families Seeking Substance Abuse and Mental Health Treatment—May 11, 2016—The Attorney General announced that it was offering assistance to New York residents and their families struggling with substance abuse or mental health disorders. The announcement encouraged those seeking treatment or facing barriers with health insurers to contact the Attorney General's Health Care Helpline for assistance with exercising their rights under Timothy's Law, which requires insurers to provide coverage for diagnosis and treatment of mental health disorders at least equal to coverage provided for other health conditions, and the federal Mental Health Parity and Addiction Equity Act, which prohibits health plans from imposing greater financial requirements or treatment limitations on mental health or substance use disorder benefits than on medical or surgical benefits. http://www.ag.ny.gov/

press-release/ag-schneiderman-offers-assistance-individuals-and-families-seeking-substance-abuse-and.

National Settlement with Olympus Corporation for $306 Million—May 2, 2016—The Federal government and multiple states reached an agreement with Olympus Corporation of Americas resolving allegations of kickbacks to health care providers. Olympus allegedly violated the False Claims Act by using improper financial incentives to induce health care providers to purchase medical equipment manufactured by Olympus, including grants, fellowships, consulting payments, free trips, and no-charge loans for equipment. New York's Medicaid Program received $7.7 million from the $306 million settlement. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-306-million-national-settlement-olympus-corporation.

Federal and State Governments Reach an Agreement with Wyeth and Pfizer for $784.6 Million to Resolve Allegation of Underpaying Rebates Owed Through the Medicaid Drug Rebate Program—April 27, 2016—Pharmaceutical company Wyeth and its corporate parent, Pfizer, reached a settlement agreement with the Federal government and multiple States, including New York, for unpaid rebates owed to Medicaid. The agreement resolves allegations that between 2001 and 2006 Wyeth underpaid rebates to the Medicaid Rebate Program for the medications Protonix Oral and Protonix IV. Out of the $784.6 million settlement, $93.7 million will resolve claims involving New York's Medicaid program, with $55.6 million going to New York State and $38.1 million going to the Federal government. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-multistate-and-federal-settlement-wyeth-and-pfizer-7846m.

Major Agreement with Seven Insurers to Expand Coverage of Hepatitis C Treatment—April 26, 2016—The Attorney General announced an agreement with Affinity Health Plan, Empire BlueCross BlueShield, Excellus Health Plan, HealthNow, Independent Health, United Healthcare/Oxford, and MVP Health Plan to expand coverage for Hepatitis C treatment. The insurers agreed to remove restrictions limiting treatment to members with advanced liver scarring or other complications, denying coverage to members using alcohol or other drugs, and only allowing specialists to authorize treatment. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-major-agreement-seven-insurers-expand-coverage-chronic.

A Binghamton-Area Transport Company Allegedly Defrauded Medicaid for over $80k—April 22, 2016—The owner of a Broome County transportation company was arrested for allegedly receiving $80,000 from Medicaid while operating without necessary licenses. Between March 2015 and January 2016, the owner allegedly failed to maintain the proper licenses to operate the taxicab service and submitted false forms indicating that the proper licenses were obtained. The owner was charged with one count of grand larceny in the second degree and with offering a false instrument for filing in the first degree. http://www.ag.ny.gov/press-release/binghamton-area-transport-company-owner-allegedly-bilked-medicaid-over-80k-operating.

Mother and Daughter Arrested for Allegedly Defrauding Medicaid for Home Health Services Not Provided—April 21, 2016—A mother and daughter in Rochester were arrested for allegedly submitting false timesheets for home care provided to their relative between September 2014 and April 2015. The mother was responsible for submitting the home health aide's timesheets to a healthcare provider that billed Medicaid, and the daughter was the home health aide providing the services to the relative. In total, the daughter received $1,490 in pay for hours she was allegedly working elsewhere. The two were arraigned on one count each of grand larceny in the fourth degree, falsifying business records in the first degree and offering a false instrument for filing in the first degree and face one to four years of imprisonment. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-mother-and-daughter-allegedly-bilking-medicaid-home.

Certified Nurse Aide Arrested for Stealing Wedding Ring of Nursing Home Resident—April 20, 2016—A Certified Nurse Aide at a Saratoga nursing home was arrested for allegedly stealing a wedding ring from a resident in July 2015 and selling it to a Ballston Spa jewelry store. The nurse aide was charged with one count of grand larceny in the fourth degree and one count of criminal possession of stolen property in the fourth degree, both class E felonies. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-capital-region-certified-nurse-aide-stealing-wedding.

Two Three-Quarter House Operators Arrested for Alleged Medicaid Fraud and Money Laundering—April 14, 2016—Two operators of New York City "three-quarter home" drug treatment programs were arrested for allegedly forcing the residents at their homes to attend specific drug treatment providers, irrespective of the residents' actual medical need for drug treatment services. The operators were charged with grand larceny in the second degree, money laundering in the second degree, and violations of the Social Services Law involving kickbacks for Medicaid services. The Attorney General's Office also filed a civil lawsuit under the False Claims Act against the two operators and is seeking over $1.9 million in damages plus penalties. The operators could face up to fifteen years in prison, if convicted. The operators allegedly submitted and received over $600,000 in illegal kickbacks through corporations they controlled for services that were often medically unnecessary. The complaint also alleged that the operators kept the three-quarter homes in abysmal conditions and subjected the residents to violence from the staff, including from the operators themselves. http://www.ag.ny.gov/

press-release/ag-schneiderman-announces-arrest-three-quarter-house-operators-yury-and-rimma-baumblit.

Nurse Arrested for Allegedly Falsifying Patient Records to Steal Medications—April 14, 2016—A registered nurse at a hospital was arrested for allegedly falsifying two patients' medical records in order to steal their medications. The nurse was charged with falsifying business records in the first degree, criminal possession of a controlled substance in the seventh degree, and petit larceny. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-nurse-charged-falsifying-patient-records-cover-her.

Attorney General Sues Health Plan for Unlawfully Denying Coverage of Hepatitis C Treatment—April 14, 2016—The New York Attorney General filed suit in New York Supreme Court alleging that a health plan unlawfully restricted coverage of Hepatitis C treatment to its members. According to the complaint, the health plan denied coverage for treatment unless the member demonstrated advanced disease such as liver scarring, and the insurer failed to disclose that it considered cost in determining whether to cover the Hepatitis C treatment. The lawsuit alleges that these practices violate the health plan's own policies and mislead members about the scope of their coverage. http://www.ag.ny.gov/press-release/ag-schneiderman-lawsuit-accuses-health-insurer-cdphp-unlawfully-denying-coverage.

Nurse Arrested for Allegedly Abusing a 94-Year-Old Female Nursing Home Resident—April 8, 2016—A registered nurse working at a Rome-based nursing home was arrested for allegedly grabbing a 94 year-old nursing home resident who suffers from advanced dementia and osteoporosis and holding the resident's arm over her head while cursing at the resident. The nurse was charged with endangering the welfare of an incompetent or physically disabled person in the first degree and wilful violation of health laws. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-rome-nurse-allegedly-physically-and-verbally-abusing.

Nurse Aide Arraigned for Pushing and Injuring a Nursing Home Resident—April 5, 2016—A certified nurse aide at a nursing home was arraigned on charges of falsifying business records in the first degree, endangering the welfare of an incompetent or physically disabled person in the first degree, and wilful violation of health laws. In October 2015, the nurse aide allegedly hit and pushed a resident and made false statements to the facility regarding the incident. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arraignment-nurse-aide-charges-striking-and-shoving-nursing.

Long Island Nurse Indicted for Allegedly Attempting to Cover Up Fall of Nursing Home Resident—April 1, 2016—A former Director of Nursing Services at a rehabilitation center was indicted for allegedly providing false records to a Department of Health investigator who was investigating a complaint. The nurse allegedly knew that a disabled resident was not being properly monitored for fall prevention, as ordered by a physician, and gave false records to the investigator indicating the resident had in fact been properly monitored. The nurse was charged with offering a false instrument for filing in the first degree and tampering with physical evidence. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-indictment-nurse-allegedly-attempting-cover-fall-nursing.

Pharmacist Pleads Guilty to Multi-Million Dollar Medicaid Fraud Scam Involving HIV Medications—March 29, 2016—A pharmacist pleaded guilty to multiple felony counts involving a nationwide scheme that sold over $274 million of diverted prescription medications. The pharmacist's company also pleaded guilty to money laundering in the first degree. New York's Medicaid Program reimbursed a pharmacy supervised by the pharmacist for over $150,000,000 in diverted medications. Additionally, the pharmacist admitted to taking over $5 million in bribes on behalf of the pharmacy. The pharmacist faces a prison sentence between two to seven years, and is required to surrender his pharmacist license and forfeit $5,456,267 to New York's Medicaid program. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-guilty-plea-pharmacist-connection-150-million-medicaid-fraud.

I-Stop Fully Implemented with Mandatory E-Prescribing—March 27, 2016—The Internet System for Tracking Over-Prescribing Act (I-STOP) became fully implemented as a universal system of e-prescribing for most prescription medications in New York. The law, which was enacted in 2012, seeks to prevent and reduce opioid abuse. http://www.ag.ny.gov/press-release/statement-ag-schneiderman-full-implemention-i-stop.

Consent Judgment Issued Against Man for Unlawful Practice of Optometry—March 23, 2016—A consent judgment was issued against an individual, a repeat offender of the unlawful practice of optometry without a license. In 2013, the individual was convicted of two felonies for defrauding Medicaid and the unauthorized practice of optometry. The new consent judgment permanently bars the individual from providing ophthalmic services, imposes $10,000 in fines, and requires the sale of the individual's company, where a random inspection in 2015 revealed that he was again offering optician services without a license. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-judgment-against-man-who-illegally-operated-optometry-shop.

Health Care Company Agrees to Discontinue Discriminatory Practices—March 10, 2016—A company has agreed to discontinue discriminatory advertising and hiring practices. The agreement follows an investigation arising from the Company's

publishing of a job advertisement seeking a female, "laid back nurse, No Haitians." The investigation also revealed other advertisements involving restrictions on male and female applicants. The agreement requires $100,000 in penalties, the adoption of new policies prohibiting discriminatory conduct, the conducting of anti-discrimination training and investigation of all complaints alleging discriminatory treatment. http://www.ag.ny.gov/press-release/ag-schneiderman-secures-agreement-stemming-%E2%80%98no-haitians%E2%80%99-classified-ad.

Pharmacy Owner Arrested for Alleged Prescription Buy-Back-and-Bill Scam—March 8, 2016—A licensed pharmacy owner, with pharmacies in Brooklyn and the Bronx, allegedly filed over $59,000 in false claims with Medicaid. The pharmacy owner allegedly paid Medicaid recipients to not receive their prescribed HIV medication and then submitted claims to Medicaid certifying that the pharmacy had dispensed the medication. The complaint charged the pharmacy owner with grand larceny in the third degree, health care fraud in the third degree, and offering a false instrument for filing in the first degree. If convicted, the pharmacy owner faces between two to seven years in prison. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-pharmacy-owner-perpetrating-alleged-prescription-buy.

Endo Pharmaceuticals Settles Charges of Improper Marketing of Prescription Opioids—March 3, 2016—The Attorney General and Endo Pharmaceuticals ("Endo") reached a settlement agreement regarding Endo's marketing of the prescription opioid drug, Opana ER. The agreement requires Endo to accurately disclose the risk of addiction associated with the drug, to summarize the studies regarding the drug on its website and to create a program that will prevent the sale of the drug to providers who may be involved in the abuse and illegal diversion of opioids. Endo also agreed to pay a $200,000 penalty. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-endo-health-solutions-inc-endo-pharmaceuticals.

Nursing Home Receptionist Pleads Guilty to Forging Resident Checks—March 2, 2016—A nursing home receptionist pleaded guilty to one count of criminal possession of a forged instrument in the second degree for forging residents' checks and stealing money from their Patient Funds Accounts while employed at the nursing home. Upon pleading guilty, the individual paid $11,600 in restitution and faces up to three years of imprisonment. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-guilty-plea-former-nursing-home-employee-charged-stealing.

New York State Office of the Medicaid Inspector General Update

Compiled by Eric W. Dyer

Governor Cuomo Announces Recommendations from Heroin and Opioids Task Force—June 10, 2016—https://www.omig.ny.gov/latest-news/905-governor-cuomo-announces-recommendations-from-heroin-and-opioids-task-force.

Governor Cuomo Announces Statewide Task Force to Combat Heroin and Prescription Opioid Crises—May 10, 2016—https://www.omig.ny.gov/latest-news/892-governor-cuomo-announces-statewide-task-force-to-combat-heroin-and-prescription-opioid-crisis.

Governor Cuomo Announces Partnership with New Jersey to Fight Prescription Drug Abuse—April 27, 2016—https://www.omig.ny.gov/latest-news/891-governor-cuomo-announces-partnership-with-new-jersey-to-fight-prescription-drug-abuse.

Continuing Education Credits Now Available for OMIG's Nine Part Compliance Elements Webinar Series—April 19, 2016—https://www.omig.ny.gov/latest-news/889-continuing-legal-education-credits-now-available-for-omig-s-nine-part-compliance-elements-webinar-series.

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OMIG Executes Corporate Integrity Agreement Covering Mid-Hudson Nursing Home Chain—March 2, 2016—https://omig.ny.gov/latest-news/887-omig-executes-corporate-integrity-agreement-covering.

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In the Law Journals

Compiled by Mishka Woodley

"An Anesthesiologist, A Brain Surgeon, And A Nurse Walk Into A Bar . . .": A Call For Change In How America Handles Health Care Worker Substance Abuse, Angelica Halat, 46 Seton Hall L. Rev. 939 (2016)

A Conceptual Framework for Thinking about Physician-Assisted Death for Persons with a Mental Disorder, Catherine S. Shaffer, 22 Psych. Pub. Pol. And L. 141 (2016)

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A Judicial Solution to the Medicaid Gap: Using Section 1983 to Do What the Federal Government Cannot, Dylan Scot Young, 84 Geo. Wash. L. Rev. 511 (2016)

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A Review Of The Sunshine Act's Open Payments Program: Are Patients Still In The Dark?, Shirley Chen, 27 Loy. Consumer L. Rev. 358 (2015)

Advance Directive Accessibility: Unlocking The Toolbox Containing Our End-Of-Life Decisions, Vanessa Cavallaro, 31 Touro L. Rev. 555 (2015)

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Crossing the Line: Daubert, Dual Roles, and the Admissibility of Forensic Mental Health Testimony, Sara Gordon, 37 Cardoza L. Rev. 1345 (2016)

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In This Issue, That Other Provision of the Anti-Kickback Statute: Should Plaintiffs and the Government Reconsider Its Potential Application and Benefits?, Andrew S. Feldman, Esq., 28 Health Lawyer 1 (2016)

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Searching For Certainty: OFCCP Jurisdiction Over Health Care Providers, Dara L. DeHaven , Leigh M. Nason, 9 J. Health & Life Sci. L. 36 (2016)

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The Federal Trade Commission And Federal Courts' Scrutiny Of Healthcare Mergers: Do Inflexible Standards And Increased Scrutiny Stifle The Legislative Intent Of The Patient Protection And Affordable Care Act?, Cory H. Howard, 18 Quinnipiac Health L.J. 67 (2015)

The Hospital Readmission Reduction Program: Fraud And Abuse Concerns, Courtney Mathews, 17 DePaul J. Health Care L. 31 (2015)

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To Promote or Not to Promote? The Enforceability of FDA's Off-Label Marketing Restrictions Following Amarin, Matthew Newcomer, Vol. 9, No. 2, J. Health & Life Sci. L. Pg. 6 (2016)

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The ABCs (Accessibility, Barriers, and Challenges) of Medicaid Expansion, 9 St. Louis U. J. Health L. & Pol'y (2016)

- *Foreword: Key Issues Facing Medicaid after the Affordable Care Act, John V. Jacobi*
- *Medicaid, Managed Care, and the Mission for the Poor, John V. Jacobi*
- *On the Expansion of "Welfare" and "Health" under Medicaid, Laura D. Hermer*

The Liberal Dilemma in Child Welfare Reform, 24 Wm. & Mary Bill of Rts. J. (2016)

- *A Liberal Dilemma Respecing Autonomy while also Protecting Inchoate Children from Prenatal Substance Abuse, Andrew J. Weisberg and Frank E. Candervort*
- *Project Prevention: Concept, Operation, Results and Controversies about Paying Drug Abusers to Obtain Long-Term Birth Control, Brice A. Thyer,*
- *Reevaluating the Criminalization of In Utero Alcohol Exposure: A Harm-Reduction Approach, Adam J. Duso and John Stogner*

Mishka Woodley, an associate at Shenker Russo Clark LLP in Albany, recently received her J.D. from Albany Law School and an M.S in Bioethics from Clarkson University / Icahn School of Medicine at Mt. Sinai.

For Your Information

By Claudia O. Torrey, Esq.

Colorado Amendment 69 (The Colorado State Health Care System Amendment [http://www.sos.state.co.us/pubs/elections/initiatives/titleE2016/20Final.pdf]) is slated for the November 8, 2016 ballot as an initiated constitutional amendment regarding the creation of "ColoradoCare" ("CC")—a health care payment system designed to finance health care for Colorado residents via an approximate $25 billion increase in state taxes. Theoretically, CC is a single-payer system that would contract with health care providers to pay for certain health care benefits as well as shoulder responsibility for administering children's health programs, Medicaid, and other health care funds. Some of the proposed covered benefits include: prescription drugs, hospitalization, medical equipment, emergency care, mental health services, maternity and newborn care, laboratory services, and end-of-life/palliative care.

Potentially becoming the first "State Resident Universal Single Payer Health Care System" in America, CC is slated to replace the medical care portion of Workers' Compensation Insurance, require no deductibles, and require no co-payments on certain primary care and preventive services. CC would also allow covered beneficiaries to remain "covered" while traveling or temporarily living in another State, as well as choose their own primary care professional. The CC is proposed as a cooperative business model wherein State residents would have "ownership" and elect a Board of Trustees; Section 1332 of the Affordable Care Act allows States to create their own health care systems and receive federal assistance via waiver.

As an interesting side issue, there is concern by some that CC might limit access to abortion services. This column was being prepared when the United States Supreme Court handed down *Whole Woman's Health et al. v. Hellerstedt, Commissioner, Texas Department of State Health Services, et al.* We shall wait and see!

Claudia Torrey is a charter member of the Health Law Section.

DSRIP Performing Provider Systems: Who They Are and What They Are Doing

Special Editor's Note—The following 25 Performing Provider Systems (PPS) were approved by the New York State Department of Health and the Centers for Medicare and Medicaid Services to participate in the Medicaid Delivery System Reform Incentive Payment (DSRIP) program. The PPSs are composed of health care providers and community based organizations who are expected to collaborate to implement specific projects aimed at reducing avoidable hospital inpatient and emergency department visits while enhancing the availability and quality of community based care and services for the Medicaid population. Each PPS has selected projects from an available menu provided by the Department of Health. The projects are intended to address the health care needs of the population served by the providers in the PPS, as identified in a community needs assessment undertaken by the PPS.

NAME	COUNTIES SERVED	ATTRIBUTED MEDICAID LIVES	$ AWARD	PROJECTS SELECTED By Domain Number See Next Table for Project List
Adirondack Health Institute, Inc.	Clinton, Essex, Franklin, Fulton, Hamilton, St. Lawrence, Saratoga, Warren, Washington	143,640	$186,715,496	2: 2.a.i, 2.a.ii, 2.a.iv, 2.b.viii, 2.d.i 3: 3.a.i, 3.a.ii, 3.a.iv, 3.g.i 4: 4.a.iii, 4.b.ii
Advocate Community Providers, Inc.	Bronx, Kings (Brooklyn), New York (Manhattan), Queens	312,623	$700,038,844	2: 2.a.i, 2.a.iii, 2.b.iii, 2.b.iv 3: 3.a.i, 3.b.i, 3.c.i, 3.d.iii 4: 4.b.i
Albany Medical Center Hospital	Albany, Columbia, Greene, Saratoga, Warren	107,781	$141,430,548	2: 2.a.i, 2.a.iii, 2.a.v, 2.b.iii, 2.d.i 3: 3.a.i, 3.a.ii, 3.b.i, 3.d.iii 4: 4.b.i, 4.b.ii
Alliance for Better Health Care, LLC	Albany, Fulton, Montgomery, Rensselaer, Saratoga, Schenectady	193,150	$250,232,844	2: 2.a.i, 2.b.iii, 2.b.iv, 2.b.viii, 2.d.i 3: 3.a.i, 3.a.iv, 3.d.ii, 3.g.i 4: 4.a.iii, 4.b.i
Bassett Medical Center	Delaware, Herkimer, Madison, Otsego, Schoharie	62,043	$71,839,378	2: 2.a.ii, 2.b.vii, 2.b.viii, 2.c.i, 2.d.i 3: 3.a.i, 3.a.iv, 3.d.iii, 3.g.i 4: 4.a.iii, 4.b.i
Bronx-Lebanon Hospital Center	Bronx	70,861	$153,930,779	2: 2.a.i, 2.a.iii, 2.b.i, 2.b.iv 3: 3.a.i, 3.c.i, 3.d.ii, 3.f.i 4: 4.a.iii, 4.c.ii

Care Compass Network	Broome, Chemung, Chenango, Cortland, Delaware, Schuyler, Steuben, Tioga, Tompkins	186,101	$224,540,275	2: 2.a.i, 2.b.iv, 2.b.vii, 2.c.i, 2.d.i 3: 3.a.i, 3.a.ii, 3.b.i, 3.g.i 3: 4.a.iii, 4.b.ii
Central New York Care Collaborative, Inc.	Cayuga, Lewis, Madison, Oneida, Onondaga, Oswego	262,144	$323,029,955	2: 2.a.i, 2.a.iii, 2.b.iii, 2.b.iv, 2.d.i 3: 3.a.i, 3.a.ii, 3.b.i, 3.g.i 4: 4.a.iii, 4.d.i
Finger Lakes Performing Provider System, Inc.	Allegany, Cayuga, Chemung, Genesee, Livingston, Monroe, Ontario, Orleans, Seneca, Steuben, Wayne, Wyoming, Yates	413,289	$565,448,177	2: 2.a.i, 2.b.iii, 2.b.iv, 2.b.vi, 2.d.i 3: 3.a.i, 3.a.ii, 3.a.v, 3.f.i 4: 4.a.iii, 4.b.ii
Maimonides Medical Center	Kings (Brooklyn), Queens	212,586	$489,039,450	2: 2.a.i, 2.a.iii, 2.b.iii, 2.b.iv 3: 3.a.i, 3.b.i, 3.d.ii, 3.g.i 4: 4.a.iii, 4.c.ii
Millennium Collaborative Care	Allegany, Cattaraugus, Chautauqua, Erie, Genesee, Niagara, Orleans, Wyoming	309,457	$243,019,729	2: 2.a.i, 2.b.iii, 2.b.vii, 2.b.viii, 2.d.i 3: 3.a.i, 3.a.ii, 3.b.i, 3.f.i 4: 4.a.i, 4.d.i
Montefiore Medical Center	Dutchess, Orange, Putnam, Rockland, Sullivan, Ulster, Westchester	105,752	$249,071,149	2: 2.a.i, 2.a.iii, 2.a.iv, 2.b.iii 3: 3.a.i, 3.a.ii, 3.b.i, 3.d.iii 4: 4.b.i, 4.b.ii
Mount Sinai PPS, LLC	Kings (Brooklyn), New York (Manhattan), Queens	136,370	$389,900,648	2: 2.a.i, 2.b.iv, 2.b.viii, 2.c.i 3: 3.a.i, 3.a.iii, 3.b.i, 3.c.i 4: 4.b.ii, 4.c.ii
NYU Lutheran Medical Center	Kings (Brooklyn)	74,326	$127,740,537	2: 2.a.i, 2.b.iii, 2.b.ix, 2.c.i 3: 3.a.i, 3.c.i, 3.d.ii 4: 4.b.i, 4.c.ii
Nassau Queens Performing Provider System, LLC	Nassau, Queens	1,030,400	$535,396,603	2: 2.a.i, 2.b.iv, 2.b.vii, 2.d.i 3: 3.a.i, 3.a.ii, 3.b.i, 3.c.i 4: 4.a.iii, 4.b.i
New York City Health & Hospitals Corporation	Bronx, Kings (Brooklyn), New York (Manhattan), and Queens	2,760,602	$1,215,165,724	2: 2.a.i, 2.a.iii, 2.b.iii, 2.b.iv, 2.d.i 3: 3.a.i, 3.b.i, 3.d.ii, 3.g.i 4: 4.a.iii, 4.c.ii

New York-Presbyterian/ Queens	Queens	12,962	$31,776,993	2: 2.a.ii, 2.b.v, 2.b.vii, 2.b.viii 3: 3.a.i, 3.b.i, 3.d.iii, 3.g.ii 3: 4.c.ii
Refuah Community Health Collaborative	Orange, Rockland	26,804	$45,634,589	2: 2.a.i, 2.a.ii, 2.c.i 3: 3.a.i, 3.a.ii, 3.a.iii 4: 4.b.i
SBH Health System	Bronx	159,201	$384,271,362	2: 2.a.i, 2.a.iii, 2.b.iii, 2.b.iv 3: 3.a.i, 3.b.i, 3.c.i, 3.d.ii 4: 4.a.iii, 4.c.ii
Samaritan Medical Center	Jefferson, Lewis, St. Lawrence	61,994	$78,062,821	2: 2.a.i, 2.a.ii, 2.a.iv, 2.b.iv, 2.d.i 3: 3.a.i, 3.b.i, 3.c.i, 3.c.ii 4: 4.a.iii, 4.b.ii
Sisters of Charity Hospital of Buffalo, New York	Chautauqua, Erie, Niagara	43,375	$92,253,402	2: 2.a.i, 2.b.iii, 2.b.iv, 2.c.ii 3: 3.a.i, 3.b.i, 3.f.i, 3.g.i 4: 4.a.i, 4.b.i
State University of New York at Stony Brook University Hospital	Suffolk	437,896	$298,562,084	2: 2.a.i, 2.b.iv, 2.b.vii, 2.b.ix, 2.d.i 3: 3.a.i, 3.b.i, 3.c.i, 3.d.i 4: 4.a.ii, 4.b.ii
Staten Island Performing Provider System, LLC	Richmond (Staten Island)	180,268	$217,087,986	Domain 2: 2.a.iii, 2.b.iv, 2.b.vii, 2.d.i Domain 3: 3.a.i, 3.a.iv, 3.c.i, 3.g.ii Domain 4:4.a.iii, 4.b.ii
The New York and Presbyterian Hospital	New York (Manhattan)	47,293	$97,712,825	Domain 2: 2.a.i, 2.b.i, 2.b.iii, 2.b.iv Domain 3: 3.a.i, 3.a.ii, 3.e.i, 3.g.i Domain 4: 4.b.i, 4.c.i
Westchester Medical Center	Delaware, Dutchess, Orange, Putnam, Rockland, Sullivan, Ulster, Westchester	573,393	$273,923,615	Domain 2: 2.a.i, 2.a.iii, 2.a.iv, 2.b.iv, 2.d.i Domain 3: 3.a.i, 3.a.ii, 3.c.i, 3.d.iii Domain 4: 4.b.i, 4.b.ii

DSRIP Projects List

Project Numbers	DESCRIPTION
	Domain 2: System Transformation Projects
A.	**Create Integrated Delivery Systems**
2.a.i	Create Integrated Delivery Systems that are focused on Evidence-Based Medicine/ Population Health Management
2.a.ii	Increase certification of primary care practitioners with PCMH certification and/or Advanced Primary Care Models (as developed under the NYS Health Innovation Plan (SHIP))
2.a.iii	Health Home At-Risk Intervention Program: Proactive management of higher risk patients not currently eligible for Health Homes through access to high quality primary care and support services
2.a.iv	Create a medical village using existing hospital infrastructure
2.a.v	Create a medical village/alternative housing using existing nursing home infrastructure
B.	**Implementation of Care Coordination and Transitional Care Programs**
2.b.i	Ambulatory Intensive Care Units (ICUs)
2.b.ii	Development of co-located primary care services in the emergency department (ED)
2.b.iii	ED care triage for at-risk populations
2.b.iv	Care transitions intervention model to reduce 30 day readmissions for chronic health conditions
2.b.v	Care transitions intervention for skilled nursing facility (SNF) residents
2.b.vi	Transitional supportive housing services
2.b.vii	Implementing the INTERACT project (inpatient transfer avoidance program for SNF)
2.b.viii	Hospital-Home Care Collaboration Solutions
2.b.ix	Implementation of observational programs in hospitals
C.	**Connecting Settings**
2.c.i	Development of community-based health navigation services
2.c.ii	Expand usage of telemedicine in underserved areas to provide access to otherwise scarce services
D.	Utilizing Patient Activation to Expand Access to Community Based Care for Special Populations
2.d.i	Implementation of Patient Activation Activities to Engage, Educate and Integrate the uninsured and low/non-utilizing Medicaid populations into Community Based Care
	Domain 3: Clinical Improvement Projects
A.	**Behavioral Health**
3.a.i	Integration of primary care and behavioral health services
3.a.ii	Behavioral health community crisis stabilization services
3.a.iii	Implementation of evidence-based medication adherence programs (MAP) in community based sits for behavioral health medication compliance
3.a.iv	Development of Withdrawal Management (e.g., ambulatory detoxification, ancillary withdrawal services) capabilities and appropriate enhanced abstinence services within community-based addiction treatment programs
3.a.v	Behavioral Interventions Paradigm (BIP) in Nursing Homes

B.	**Cardiovascular Health—Implementation of Million Hearts Campaign**
3.b.i	Evidence-based strategies for disease management in high risk/affected populations (adult only)
3.b.ii	Implementation of evidence-based strategies to address chronic disease – primary and secondary prevention projects (adults only)
C.	**Diabetes Care**
3.c.i	Evidence-based strategies for disease management in high risk/affect populations (adults only)
3.c.ii	Implementation of evidence-based strategies to address chronic disease – primary and secondary prevention projects (adults only)
D.	**Asthma**
3.d.i	Development of evidence-based medication adherence programs (MAP) in community settings – asthma medication
3.d.ii	Expansion of asthma home-based self-management program
3.d.iii	Implementation of evidence-based medicine guidelines for asthma management
E.	**HIV/AIDS**
3.e.i	Comprehensive Strategy to decrease HIV/AIDS transmission to reduce avoidable hospitalizations – development of a Center of Excellence for Management of HIV/AIDS
F.	**Perinatal Care**
3.f.i	Increase support programs for maternal & child health (including high risk pregnancies) (Example: Nurse-Family Partnership)
G.	**Palliative Care**
3.g.i	Integration of palliative care into the PCMH Model
3.g.ii	Integration of palliative care into nursing homes
H.	**Renal Care**
3.h.i	Specialized Medical Home for Chronic Renal Failure
	Domain 4: Population-wide Projects: New York's Prevention Agenda
A.	**Promote Mental Health and Prevent Substance Abuse (MHSA)**
4.a.i	Promote mental, emotional and behavioral (MEB) well-being in communities
4.a.ii	Prevent Substance Abuse and other Mental Emotional Behavioral Disorders
4.a.iii	Strengthen Mental Health and Substance Abuse Infrastructure across Systems
B.	**Prevent Chronic Diseases**
4.b.i	Promote tobacco use cessation, especially among low SES populations and those with poor mental health
4.b.ii	Increase Access to High Quality Chronic Disease Preventative Care and Management in Both Clinical and Community Settings (Note: This project targets chronic diseases that are not included in domain 3, such as cancer)
C.	**Prevent HIV and STDs**
4.c.i	Decrease HIV morbidity
4.c.ii	Increase early access to, and retention in, HIV care
4.c.iii	Decrease STD morbidity
4.c.iv	Decrease HIV and STD disparities
D.	**Promote Health Women, Infants and Children**
4.d.i	Reduce premature births

Source: NY DSRIP Project Toolkit

Governance Issues in New York State's Delivery System

Reform Incentive Payment Program

By Jeffrey C. Thrope

A key element of the New York State Delivery System Reform Incentive Payment Program ("DSRIP") is the creation of Performing Provider Systems ("PPSs") to carry out DSRIP Projects designed to improve the health of the population covered by Medicaid, as well as the uninsured, and thereby, to reduce avoidable emergency room and inpatient utilization. The concept of the PPS is to create a mechanism to encourage collaboration among providers, including hospitals, physicians, nursing homes, and many other types of health care providers, as well as community based organizations ("CBOs"). While most of the twenty-five PPSs participating in New York's DSRIP Program are anchored by hospitals, at least one is led by physician groups and Independent Practice Associations, in partnership with hospitals and other providers. In addition, several of the PPSs have created new entities to serve as the PPSs.

While it will not be covered here in detail, the basic goal of New York's DSRIP Program is to reform the delivery system, through incentive payments, and thereby to facilitate improvement in population health. This effort is designed to achieve the further goal of reducing avoidable emergency room and inpatient utilization by 25% over the five year DSRIP period, and to move 90% of Medicaid enrollees into Value-Based Payment arrangements by the end of the DSRIP period.

This article will address the governance requirements and concepts incorporated into the New York DSRIP Program, as well as some of the challenges presented by those requirements and concepts. As will be seen, the concept of governance goes beyond the normal entity governance concepts with which lawyers are familiar, and encompasses consultation, input, and potentially decision-making by a broad group of health care providers, community-based organizations and other stakeholders.

DSRIP Background

Any review of the requirements and concepts applicable to the DSRIP Program should start with the foundational documents that contain the concepts and requirements of the Program. New York's DSRIP Program is technically an "1115 Waiver" that authorizes the State's Medicaid Program to experiment with innovative approaches that go beyond the traditional fee-for-service model set forth in the federal Medicaid statute.

The key foundational documents are an agreement between New York State (NYS) and the Centers for Medicare and Medicaid Services ("CMS") known as the Special Terms and Conditions. The elements of the New York DSRIP Program are set forth in the Special Terms and Conditions.[1] Attachments to the Special Terms and Conditions cover many of the operational details, as follows:

- Attachment I: Program Funding and Mechanics Protocol.
- Attachment J: Strategies and Metrics Menu.
- Attachment K: DSRIP Operational Protocol.
- Attachment L: DSRIP Quarterly Report Guidelines.

Additional guidance is provided in many documents, PowerPoint Presentations and Frequently Asked Questions documents on the New York State Department of Health's DSRIP Website. Finally, more guidance is provided in the Implementation Plan Guidance for evaluation and scoring of the "Achievement Values" that determine whether the PPS receives the maximum DSRIP award or a lesser amount. Indeed, the governance measures are so important that they count for 30% of the score of each Project undertaken by the PPSs.

As an initial matter, it should be understood that DSRIP only covers Medicaid and the uninsured individuals and families. Unlike a traditional grant program, DSRIP is an "incentive" program, which provides "bonus" or "incentive" payments based on achievement of defined metrics and milestones. As a program approved as an 1115 Waiver, DSRIP is not subject to the generally applicable laws and regulations applicable to the Medicaid Program. As noted above, the New York DSRIP Program is based on an agreement between NYS and CMS known as the "Special Terms and Conditions." Under that agreement, payments to PPSs and their constituent entities are tied to each PPS's achievement of metrics and milestones. The "awards" issued to each PPS based on the Attribution for Valuation process represent the maximum funding level, subject to achievement of an extensive set of metrics and milestones.

The Special Terms and Conditions (page 39) define the DSRIP organizational goals as follows:

> DSRIP funding is available to Performing Provider Systems that consist of safety net providers whose project plans are approved and funded through the pro-

> cess described in these STCs and who meet particular milestones described in their approved DSRIP project plans. DSRIP project plans are based on the evidenced-based projects specified in the DSRIP Strategies Menu and Metrics (Attachment J) and are further developed by Performing Provider Systems to be directly responsive to the needs and characteristics of the low-income communities that they serve and to achieve the transformation objectives furthered by this demonstration.

This concept is spelled out in more detail in Attachment I to the Special Terms and Conditions, in relevant part:

> Eligible major public general hospitals and other safety net providers are encouraged to form coalitions that apply collectively as a single Performing Provider System. The state will review each of the proposed Performing Provider Systems and may require additional connectivity to additional medical, behavioral health, long term care, developmental disabilities or social service providers as required to build a comprehensive regional performance network. Coalitions will be evaluated on performance on DSRIP milestones collectively as a single Performing Provider System. Coalitions are subject to the following conditions:
>
> i. Coalitions must designate a lead coalition provider who is primarily responsible for ensuring that the coalition meets all requirements of performing provider systems, including reporting to the state and CMS. In the process of formally approving each Performing Provider System, the state shall articulate a set of standards that each lead entity must follow including specific rules on project oversight, performance payment distribution and other required legal and operational obligations of the lead entity.
>
> ii. Coalitions must establish a clear business relationship between the component providers, including a joint budget and funding distribution plan that specifies in advance the methodology for distributing funding to participating providers. . . .
>
> iii. Coalitions must have a plan for reporting, decision-making, change management, and dispute resolution on performance and incentive payments. . . .
>
> vi. Each coalition must have a data agreement in place to share and manage patient level data on system-wide performance consistent with all relevant HIPAA rules and regulations.

Discussion and implementation of the DSRIP Program requires facility with a large number of definitions and acronyms, the most important of which are as follows:

> *Attribution for Valuation*: the number of individuals assigned to a Performing Provider System, based on a "loyalty" assessment and other actors identified in the Special Terms and Conditions approved by CMS. The number of attributed individuals was a key factor in determining the amount of the "award" of DSRIP Funds to each PPS.
>
> *Attribution for Performance*: In contrast to attribution for valuation, specific individuals are attributed to each PPS for purpose of monitoring the implementation of the DSRIP Projects. This list of attributed individuals will change over the 5-year DSRIP period, as people join or leave the Medicaid program in New York State.
>
> *CBO*: Community-Based Organizations that have agreed to join a particular PPS and to work on one or more of the PPS's projects.
>
> *CMS*: The federal Centers for Medicare and Medicaid Services, the agency responsible for oversight of the Medicaid Program, and 1115 Waivers, including the NY DSRIP Waiver.
>
> *DOH*: New York State Department of Health is the New York State agency responsible for the operation of the Medicaid Program, as well as the DSRIP Program.
>
> *DSRIP*: Delivery System Reform Incentive Payment Program approved by

CMS as an "1115 Waiver," which permits experimentation by States.

DSRIP Website: DOH has developed an extensive website, on which many of the relevant materials can be found. The address is: https://www.health.ny.gov/health_care/medicaid/redesign/dsrip/

Enrollee: In this context, the term Enrollee is used to refer to individuals who are recipients of Medicaid benefits.

Independent Assessor: Public Consulting Group has been engaged by DOH to review and evaluate DSRIP Applications, Implementation Plans and Quarterly Reports.

Metrics and Milestones: A defined set of goals to be achieved by each PPS for each DSRIP Project, all supporting the overall goal of reducing avoidable Emergency Department visits and avoidable inpatient admissions by 25% over the 5-year DSRIP period.

Participating Provider: a facility, physician or other healthcare provider that has agreed to join a particular PPS and to work on one or more of the PPS's projects.

Performing Provider System ("PPS"): a group of providers and community-based organizations that have joined together to participate in one or more DSRIP Projects.

STCs: Special Terms and Conditions Agreement between CMS and NYS. This Agreement sets forth the terms on which CMS approved the New York's DSRIP Waiver. It constitutes pages 44-81 of a larger agreement between NYS and CMS. Available at: http://www.health.ny.gov/health_care/medicaid/redesign/dsrip/docs/2015-10-01_special_terms_and_conditions.pdf.

VBP: Value-Based Payments, which are the subject of a NYS Roadmap that has been approved by CMS and seeks to meet the goal of having 90% of Medicaid Enrollees in VBP arrangements by the end of the DSRIP period.

DSRIP Governance Concepts and Requirements

The DSRIP Governance concepts and requirements can be divided into two categories: first, governance of the PPS entity, covering basic formation and decision-making by the PPS, and second, broader policy governance concepts that address how the PPS and the many collaborating entities and providers in the PPS set policies and procedures for Project implementation, with input from the broad group of collaborating providers and entities, as well as other stakeholders.

DOH set out its basic governance concept in the instructions to the DSRIP Organizational Application:

> An effective governance model is key to building a well-integrated and high-functioning DSRIP PPS network. The PPS must include a detailed description of how the PPS will be governed and how the PPS system will progressively advance from a group of affiliated providers to a high performing integrated delivery system, including contracts with community-based organizations.
>
> A successful PPS should be able to articulate the concrete steps the organization will implement to formulate a strong and effective governing infrastructure.

General Corporate Governance

Each PPS has a designated lead entity. As noted, many of the lead entities are hospitals or hospital systems. Thus, the governing body of the PPS could be the Board of Directors of the hospital or health system. Alternatively, in many cases, the governing body is the Board of a separate entity, generally assumed to be a newly formed entity ("Newco") created for the purpose of serving as the lead entity of the PPS. However, it should be noted that, in at least one case, a previously existing affiliated corporation was used as the PPS entity.

The governing body for each type of PPS derives from the structure of the entity that has been selected. Corporations would have Boards of Directors appointed by stockholders in a for-profit corporation, and members or a self-perpetuating Board in a not-for-profit corporation or a for-profit corporation. Similarly, a Limited Liability Company would have a Board of Managers that serves as its governing body. Regardless of the corporate form, the governing body's composition might be determined by the single sponsoring entity, or, where multiple entities are coming together to form the PPS, by negotiations among the entities joining together in a single PPS. In addition, some of the PPSs have included representa-

tives of major Participating Providers or others on their governing body.

Once formed, the governing body would have responsibility for major decisions within the PPS, based on recommendations from governing body subcommittees, the Project Advisory Committee, and more broadly from other participants in the policy governance structure within the PPS. Quorum and voting requirements are set forth in the applicable governing documents (By-Laws, Operating Agreements, etc.). Finally, the governing documents for each entity would define the major decisions that may require stockholder or member approval.

The next governance level in most entities is a subcommittee structure. In DSRIP, the New York State Department of Health mandated that each PPS have at least the following four subcommittees: Finance, Clinical Quality Oversight, Information Technology/Data, and Workforce. The Finance Subcommittee is responsible for overseeing the finances of the PPS, as well as the important functions of developing a funds flow methodology and developing an approach to assessing providers within the PPS whose financial pressures could have a negative impact on the sufficiency of the PPS's network of Participating Providers. The Clinical Oversight Subcommittee is responsible for making sure that clinical issues are addressed and evaluated as the DSRIP Projects are implemented. The IT/Data Subcommittee is charged with overseeing the IT and data sharing mechanisms within the PPS, perhaps the most challenging element. Finally, the Workforce Subcommittee is responsible for performing assessments of the current workforce within the PPS, and the potential shifts in workforce roles that are expected to result as the DSRIP Projects have their expected effects.

These four committees have been mandated by DOH for every PPS, but, consistent with the emphasis in the DSRIP Program on input from Participating Providers, CBOs and stakeholders, individuals participating in these committees do not need to be members of the governing body. In this way, input by the broader groups participating in the PPS begins to have an impact on policy making and oversight in these key areas that are crucial to implementation of the DSRIP Projects with respect to the population assigned to the PPS through the Attribution for Performance process.

PPS Policy Governance

Throughout the development of the New York DSRIP program, the term governance most often has been used in a much broader sense than the basic entity governance models discussed above. Rather, in the New York DSRIP Program, governance is meant to refer to the way in which each PPS develops policies, procedures and approaches as it plans for and carries out the DSRIP Projects, manages DSRIP incentive payments, when earned, and seeks to achieve the goals and objectives of the DSRIP Program. As noted in the quotation from the New York DSRIP Application, these approaches are meant to foster collaboration, and to benefit from input from a broad range of Participating Providers, CBOs and other stakeholders.

Consistent with this approach, even before the DSRIP Applications were filed, the New York DSRIP Program required that each proposed PPS establish a Project Advisory Committee ("PAC"). The PAC is another DOH-mandated committee composed of representatives of the Participating Providers, CBOs, workforce representatives and unions, local government officials and other stakeholders. Each proposed PPS was required to establish a PAC from the outset, as a forum for input from these broadly defined groups. The first major element of input was the Community Needs Assessment, which each proposed PPS was required to conduct, in order to identify unmet needs in their specific communities. The Community Needs Assessment was designed to help each PPS determine which DSRIP Projects would be most beneficial in the geographic area and enrollee population to be covered by the PPS. In many cases, the PACs participated in selection of the PPSs' DSRIP Projects, or at a minimum in identifying Projects that would benefit the community and which were recommended to the PPSs' governing bodies. After the DSRIP applications were submitted and evaluated, and as the PPSs became operational and began to implement the DSRIP Projects, the PACs continued to serve as a forum for bi-lateral communication between PPSs and their Participating Providers, CBOs and stakeholders.

On the DSRIP Project level, PPSs have taken many approaches to Project Committees. However, in general, Project Committees are the groups charged with carrying out the Projects, both directly and in collaboration with the other providers and entities participating in the PPS. Project Committees have taken the lead on the development of polices and protocols for Project Implementation, consistent with the standards imposed in the New York DSRIP Program. The extent to which decision-making is delegated to the Project Committees depends on the individual PPS, but it is expected that major policy decisions would be required to be presented to the PPS governing body for approval, on recommendation from the Project Committees, as well as the governing body subcommittees. As already noted, major decisions may require stockholder or member approval, based on the specific organizational documents of particular PPSs. However, the PACs and Project Committees provide the forum for Participating Providers, CBOs and other stakeholders to

have significant input into implementation of the DSRIP Projects.

Next Steps—Value-Based Payments

As the twenty-five PPSs have begun to implement the DSRIP Projects, they are simultaneously beginning to work toward the State's goal of moving 90% of Medicaid beneficiaries into Value-Based Payment arrangements that put the providers at risk for improving population health and thereby reducing cost. The State's initial concept was that PPSs would evolve into larger, fully integrated systems, with a single overall governance structure for all purposes, at which point it would be natural for the entities participating in the PPSs to begin to negotiate managed care contracts together for Medicaid and other third party payors. Whether this vision comes to fruition is unclear at this point. However, in many cases, it is likely that the participating hospitals and other providers collaborating for DSRIP purposes will remain independent, and therefore will continue to negotiate managed care contracts on their own. Yet, even as ongoing independent entities, the increased interconnections, enhanced care management and collaboration on improving population health, as well as joint policy-making through the DSRIP Policy governance approach, will put those providers in a better position to develop, negotiate and implement Value-Based Payment arrangements.

Conclusion

As should be clear from the foregoing discussion, in addition to traditional governance structures for the PPS entity, DSRIP requires each PPS to have more extensive policy governance approaches in place, so that Project Implementation will benefit from input, involvement and collaboration among the full range of Participating Providers and Community-Based Organizations, government officials and other stakeholders, and thereby improve the chances that the PPS's implementation of the DSRIP Projects will be responsive to community needs and will achieve the goals of the DSRIP Program.

Endnote

1. The Special Terms and Conditions and other CMS materials, and revisions proposed by New York State, are available online at: http://www.health.ny.gov/health_care/medicaid/redesign/dsrip/cms_official_docs.htm.

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Antitrust Issues Under the New York DSRIP Process

By David J. Oakley and Martin J. Thompson

The unfolding process in the New York Medicaid Delivery System Reform Incentive Payment Program (DSRIP), the work of the resulting regional Performing Provider Systems (PPSs), and the move towards value-based payments (VBP) with health plans, is all predicated on certain assumptions. Those assumptions include, but are not limited to: providers should collaborate more with each other; some clinical and/or administrative services should be shared among providers; some institutional downsizing needs to occur while ambulatory care capacity is expanded; "silos" within the health care world should be breached, and economies of scale should be achieved.

While many observers of the New York health care system (including counsel) can find much to agree with in those assumptions, it is important to remember that many health care providers (and other parties) may nevertheless compete with each other to attract and serve patients. That competition means the antitrust laws must be considered. Despite the enormous flow of DSRIP grant funds to PPSs and other parties, and despite the New York State Department of Health (NYSDOH) commitments to the Centers for Medicare and Medicaid Services to transition health plan claims payments into VBP contracts with providers, antitrust laws governing interactions between competitors continue to apply, unless and until a viable exemption is identified.

The DSRIP transformation process presents two key antitrust issues to counsel. The first is obvious: there are certain situations where competitors cannot collaborate or share certain information with each other without violating the antitrust laws. The second is not so obvious: there is much that competitors can do without violating the antitrust laws. Unduly strict or uninformed antitrust advice to clients could inadvertently thwart the health reform process. Furthermore, it is not unheard of for antitrust law to be used as a convenient excuse for a certain party or management executive to (for their own reasons) decline to collaborate, when in fact collaboration is legally permitted or could be lawfully arranged. Thus a thoughtful counsel must know when to remind clients that enthusiasm for health reform should not be allowed to obscure important antitrust limits, and when to explain to clients that in fact the antitrust laws may not preclude cooperative activities.

While a full antitrust analysis is beyond the scope of this article, below we attempt to highlight the major issues.[1]

1. *The key antitrust laws*. Antitrust law generally prohibits agreements to restrain trade and conduct in furtherance of such agreements. It is important to remember that in addition to federal antitrust laws there are state antitrust laws[2] as well as an antitrust bureau of the NYS Attorney General's office.

Antitrust law does not prohibit or even address discussions which do not result in anticompetitive agreements.

There is also First Amendment protection for agreements to seek government action (such as the approvals in paragraph 6 below, or to seek legislation) even if such agreements would otherwise be illegal. The First Amendment protection also gives broad immunity for the process leading up to the request for government action.

2. *Defining competitors*. A first step in antitrust analysis is to determine who competes with whom? Not all health care providers compete with each other. The two usual key steps are to define (A) what health care service (product) is being offered for sale, and (B) to define the geographic markets where those services are offered. Primary care physicians do not compete with transplant surgeons. Primary care physicians in Buffalo do not compete with primary care physicians on Long Island. The typical concern is when the two providers offer the same or similar services, and do so within a defined geographic region where patients[3] (potential buyers) could realistically choose to receive services from one provider or the other.

Collaboration and concerted action by providers who are not competitors are rarely antitrust problems.

Defining competitors is not always simple. The services of many providers do or could overlap. For example, primary care physicians often provide many of the same services as do cardiologists. Social workers, psychologists and some primary care providers may all provide mental health counseling services. Yet psychiatrists are often in such demand that they limit their practice to prescribing medications (rather than general counseling sessions) and thus do not compete with social workers or psychologists, whose scope of licensure does not usually include prescribing medications. The advent and growth of multi-specialty medical practices (and federally qualified health centers or other clinics) creates a range of competition that may far exceed the competition which might be implied by the name of the practice. The increased use of telehealth and email-based patient/provider interactions may expand the geographic region in which providers

realistically compete with each other to attract and serve patients.

3. *What competitors cannot usually do*. Most problems posed by collective behavior by competitors relate to pricing and other monetary issues. Discussion of fees charged, or fees the provider is willing to accept, may constitute evidence of collusive price fixing. When subsequent conduct is consistent with price fixing, the agreement may be inferred. Agreements by competitors to boycott health plans or other payors unless and until the health plan pays fees above a particular level also constitute price fixing. Similar discussions or agreements regarding terms and conditions of contracts with health plans which directly impact revenues from those health plans (such as utilization review protocols or utilization review approval standards for a particular procedure) also may constitute price fixing.

Agreements not to compete are prohibited as well. Thus an agreement that one orthopedic practice will serve only patients with leg and other lower extremity issues, while the other orthopedic practice will serve only patients with arm and upper extremity issues, are prohibited. The same is true for agreements to restrict their respective practices to differing geographic regions.

4. *What competitors can usually do*. In general, discussions to improve patient care are not prohibited. Similarly discussion among providers to cooperate when rendering care in order to render better care or more efficient care to shared patients are not prohibited either. The key is that (prior to attaining formal "clinical integration" status, see paragraph 7 below) such agreements should be non-binding so that one or more parties is free to subsequently change course if the initial agreement turns out to not be as productive or beneficial as originally assumed by the disappointed provider.

A. Discussions to measure and improve quality of care (or establish care protocols) would not typically be prohibited, even among competitors. The parties might feel that such an agreement (when reduced to writing) should also be legally binding, but that binding aspect is not necessarily required for the written agreement to be fruitful, and the binding aspect injects antitrust concerns. A consensus document (which applies unless and until the consensus deteriorates) may well be more than sufficient for many DSRIP health reform purposes.

B. Discussions about delivery system change pursuant to DSRIP can usually occur without special legal protections. Those discussions could include issues such as applying for governmental action to orchestrate proposed market allocation (Hospital A is directed to provide all obstetrical services and Hospital B is directed to provide all orthopedic services) or mergers and acquisitions (Hospital C will close, while Hospital D will be acquired by Hospital E). When the discussions occur in anticipation of a subsequent State application and approval process, such as the State DSRIP funding process and State RFPs for capital assistance, those discussions enjoy broad immunity from antitrust prohibitions, even if they result in a decision among competitors to seek government action which will reduce competition. The important point is that the discussions must remain as mere discussions and/or as tentative commitments. No actual implementation can occur at this stage.

C. Out of an abundance of caution, many parties avoid even the discussion stage listed in B above. That is usually out of a concern that the conduct of some of the discussion participants may create the appearance of implementation, or because (despite legal advice) some parties may actually proceed to implementation. However, in the context of the State's DSRIP process, and assuming the parties can be trusted to in fact avoid implementation, the discussion phase is permitted under the antitrust laws. A written agreement reflecting the parties consent to a reform plan proposal is usually also permitted, so long as the agreement notes that implementation is contingent upon obtaining subsequent state approvals.

While an abundance of caution is frequently the wise course when antitrust is concerned, that caution should perhaps not be overplayed if the result of that abundance of caution thwarts the intended DSRIP health reform process.

One method to proceed regarding B above is to make a record that the parties understood the distinctions listed above. To do so it is helpful during the discussion and exploration phase to place on the record some indication of intent to comply with antitrust laws. An announcement can be included on all written agendas regarding regional planning, and can be announced by the Chair at the beginning of each meeting regarding regional planning. The announcement could note that the purpose of the meeting is for planning and that no implementation can occur until subsequent State approvals are obtained. Another method is for counsel to attend the meetings and interject to terminate the discussions if the discussions veer into prohibited territory.

5. *Data sharing*. The DSRIP process involves extensive review of data, probably from numerous sources. Data likely related to prohibited collective activity by competitors (such as fees charged or accepted from health plans) is particularly sensitive. It is important to sensitize IT staff and data analytic staff to those data components in particular. That data should not be shared or circulated in a fashion which permits competitors to see each other's competitively sensitive data. Sensitive data can be excluded from circulation, protected from access by PPS partici-

pants, or handled by an independent third party subject to non-disclosure obligations. It is important to educate PPS data analytic staff that there are frequently multiple uses of a data set. The use by the data analytics team for health reform purposes may not be the same use as by one competitor to compete with or collude with another competitor.

6. *State Action Protections*. Actions which are otherwise prohibited by the antitrust laws will be permitted if the State has implemented a state policy to replace competition with a regulatory regime and supervised those actions in a particular manner. To do so the State must have (A) specifically addressed the proposed actions and (B) conduct sufficient state supervision of the implementation to satisfy legal standards for a state action exemption. This is referred to as the state action doctrine.[4] Conduct which could be exempt as state action when adequately supervised could include such things as market allocation (Hospital A agrees to provide all obstetrical services and Hospital B agrees to provide all orthopedic services) or mergers and acquisitions (Hospital C will close while Hospital D will be acquired by Hospital E). It is important to note that the state action protection applies under federal antitrust laws, even though the determination is made by state officials. The joint federal/state protection makes the state action protections particularly valuable.

The key issue is articulating the state policy and its application in a clear and documented fashion.[5] State policy on the matter must be clear, and the State must also actively supervise the results over time to assure the implementation remains essentially in the form it was intended to occur.

Sufficient documentation of "State action" may occur in numerous forms. The options include:

A. A specific approval expressly intended to confer antitrust protection. A Certificate of Public Advantage (COPA) is a state document (and application process) created for the express purpose of conferring state action protection. New York has a COPA statute[6] and implementing regulations.[7] The statute, which amended the Public Health law authorizing the DOH Commissioner to provide state action immunity for certain activities undertaken by health care providers and others (including payors), has a particularly sweeping statement of legislative intent regarding health reform.[8] Similar state action certificates are available upon special application by accountable care organizations (ACOs) certified under the State ACO regulations.[9]

Antitrust officials and parties such as health plans are not usually enamored of COPAs, since the issuing State agency, in New York's case, DOH, essentially trumps the role of U.S. Department of Justice (USDOJ), the Federal Trade Commission (FTC) or the New York Attorney General as the lead arbiters of antitrust policy. Thus, applicants for a COPA should likely be prepared to be good advocates for their application. That likely includes a persuasive written narrative. Applicants with successful experience to date will presumably be more likely to have their application granted than those attempting (whatever it is) for the first time. Be prepared for active resistance from other parties or antitrust agencies. Be prepared to carefully document during the subsequent implementation phase (assuming you do in fact obtain the COPA approval) both success in achieving what was proposed, as well the absence of negative, countervailing effects of your proposal. Obtaining a COPA is unlikely to be a simple process.

While the COPA process is frequently thought of as involving only providers of care, the language of the statute and regulations is broad enough to include a variety of players, including health plans.[10]

B. State approval of a DSRIP application or a State capital funding RFP award *may* be sufficient. The written award from the State (together with the explicit requests set forth in the application to the State) may in theory constitute sufficient documentation of the State approval. However, regulators and courts[11] may impose a very high burden on the state supervision, the details of which have not been specifically addressed in the case law. In light of this uncertainty the COPA process is likely the safer approach.

C. Possible other State approvals (such as letters in response to an applicant's inquiry) may be requested and granted. However, for the most part it appears NYSDOH prefers to use the COPA process for requests specifically linked to the DSRIP and PPS process. Here again, the uncertainty of this informal approach probably renders the COPA process the safer approach.

7. *The leap from PPS efforts to actual VBP contracting with health plans.* While the antitrust aspects of provider contracting with health plans is beyond the scope of this article, a few points should be noted since VBP contracting is one of the long-term goals of DSRIP and the PPS efforts. As noted at the outset, collective and concerted behavior by providers who are not competitors does not typically invoke antitrust concerns. Antitrust concerns arise when competitors join together to negotiate collectively with payors over financial issues, or operational issues (such as utilization controls) with a strong linkage to financial impact.

The legal basis for collective contracting efforts by competitors with a health plan is usually that the collective efforts of the competitors (and associated non-

competitors) constitute a sort of joint venture. The shared future of the parties (at least as related to the particular contract) as a result of the joint venture permits collective behavior that is otherwise denied to outright competitors. Thus, a joint venture of sorts can arise under either of two approaches:

A. "Financial integration" occurs where the parties share sufficient financial upside and/or downside from the joint venture. Examples include a 20% withhold from fees that may or may not be returned at year end, depending upon attainment of predetermined spending, quality or other targets. Another example is full risk capitation such as health plan payment of $100 per member per month which may or may not be sufficient to compensate providers at the level providers are typically compensated at.

B. "Clinical integration" requires an extensive and genuine integration of key quality and utilization practices among providers who are otherwise separate, unaffiliated entities. The exact level of required integration is a murky standard. A key opinion by the FTC in this regard was a situation in Rochester, New York, where clinical integration was held to exist.[12] A benefit to ACOs is that ACOs approved under the Medicare ACO program are deemed by USDOJ and FTC to be clinically integrated for the purposes of federal antitrust laws.[13] A benefit to ACOs certified under the New York ACO regulations is that a New York certified ACO is deemed to be clinically integrated for the purposes of state antitrust laws.[14] In a clinically integrated setting care improvement protocols can be mandatory.

The competing parties need only be financially integrated or clinically integrated; there is no need to meet both standards. A difficulty is that there is no formal application process to obtain approval as meeting one or both standards. The parties need to consult their counsel in order to determine for themselves whether the standards are met in their particular case.[15]

In the case of both financial integration and clinical integration, the safe harbor or deemed status may not be available when the entity has particularly large market share or engages in specified behaviors which antitrust officials do not condone.

8. *Conclusion*. There are numerous danger zones for DSRIP and PPS activities which focus solely on collaboration or restructuring without regard to situations that involve competitors. On the other hand, there are numerous opportunities for alert counsel to assist clients in successfully navigating the DSRIP and PPS process to attain health reform even when competitors are part of the collaboration.

Endnotes

1. This article is intended as a primer on key antitrust issues. Antitrust law is particularly fact-specific. Thus the reader should consult his or her own counsel in order to obtain useful legal advice for one's own particular situation.
2. Article 22 of the General Business law.
3. And in some cases, health plans recruiting participating providers.
4. FTC v. Ticor Title Ins. Co., 504 U.S. 621 (1993); FTC v. Phoebe Putney Health Sys. Inc., 133 S. Ct. 1003 (2013); N. Carolina State Bd. of Dental Exam'rs v. FTC, 135 S. Ct. 1101 (2015).
5. As well as the necessary ongoing State involvement sufficient to meet legal requirements.
6. Public Health Law Article 29-F.
7. 10 NYCRR Part 83-1.
8. *See* Chapter 59 of the Laws of 2011, Part H, Section 50 (pages 146-147) for the statement of legislative intent which does not appear in the Public Health law Art 29-F.
9. Public Health Law Section 2999-n, PHL 2999-r, and 10 NYCRR Part 1003.14 (a) (2). Thus ACOs have two different (but similar) routes to obtain state action protection.
10. *See* definitions in 10 NYCRR Part 83-1.1 (c) and (g) where payors could be included.
11. State of North Carolina v. PIA Asheville, 722 F.2d 59 (1983).
12. https://www.ftc.gov/.opinions/gripa.pdf Federal Trade Commission Sept. 17, 2007.
13. Federal Register October 28, 2011 page 67026.
14. 10 NYCRR Part 1003.14 (a) (1).
15. Opinions from regulatory agencies are available in some cases. Those opinions may take some time to procure.

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Compliance in an Era of Federal and State Health Reform: Fitting a Square Peg in a Round Hole

By Tracy E. Miller

Aligned with health reform policies adopted by the Affordable Care Act, state governments have relied upon the purchasing power of Medicaid programs to advance health system transformation. To date, eight states have implemented the Delivery System Reform Incentive Payment Program (DSRIP) in some form as the primary vehicle to attain Medicaid and health system reform. The federal Centers for Medicare and Medicaid Services (CMS) has indicated that it regards New York State's program as the leading model.[1]

With $8.25 billion in funds from the federal and state governments, New York State's DSRIP program is staggering in the magnitude of its size, ambitions to reengineer the delivery system, and the speed at which it aims to achieve system redesign. The twenty-five organizations chosen as the leads (PPS Leads) for Performing Provider Systems (PPSs) in the State have been expected over the past two years to: (i) design integrated delivery systems comprised of hundreds, and in some cases thousands, of providers and social service organizations; (ii) develop detailed plans for six to 11 projects that engage providers in their PPS; (iii) build the infrastructure and analytic capacity for population health management; (iv) create and manage a representative governance structure; (v) enter into contracts covering the five-year term of DSRIP that span financial, governance, clinical, data sharing, and compliance arrangements; and (vi) determine how best to coordinate care and share data across the continuum of care.[2] PPSs will be paid in the first DSRIP years primarily based on pay-for-reporting, with payments transitioning over the five-year DSRIP term to payments for performance, weighted toward reducing preventable hospital admissions and use by 25%. Over the life of DSRIP, PPSs are also expected to transition to value-based payment arrangements with Medicaid managed care organizations, which will depend in turn on performance incentives that align payments to participating organizations with PPS incentives.

Embedded in the challenge of building the infrastructure and managing the operations of an emerging delivery system comprised of hundreds of disparate providers and social service agencies is the requirement that each PPS establish and operate an effective compliance program in accordance with New York State law, and address the myriad compliance issues that arise. Those issues are posed by Medicaid payments for the novel projects and services PPSs must deliver, the flow of those funds to participating organizations, and the fraud and abuse issues that arise in arrangements that, by design and intention due to explicit DSRIP goals, seek to change the referral patterns of patients among providers, effecting a shift from the inpatient to outpatient setting to reduce preventable hospital admissions and use.

Notably, PPSs and participating providers in DSRIP must tackle these compliance challenges without the benefit of the waivers as provided by federal agencies for the Medicare Shared Savings Program (Shared Savings Program) for accountable care organizations (ACOs). Specifically, ACOs in the Shared Savings Program operate with waivers from CMS and the United States Department of Health and Human Services (HHS), Office of Medicaid Inspector General, with respect to the application of the Stark Law, the Anti-Kickback Law (AKS) and the Civil Monetary Penalties Law (CMP) for the innovative payment arrangements that the Shared Savings Program seeks to foster.[3] In addition, the Internal Revenue Service provided guidance that applies to the disbursement and use of funds by participating exempt organizations. The Federal Trade Commission and the Department of Justice issued joint guidance related to anti-trust compliance, another major area of compliance that PPSs must address.[4]

Building a Compliance Program Across the Continuum

PPSs have by and large proceeded with two distinct corporate models; some PPSs formed unincorporated governance structures within hospitals or hospital systems, with a PPS governing body comprised of representatives from participating providers overseen by the board of the hospital or system. Other PPSs comprised of multiple hospital systems or other providers formed a new corporation (Newco) to govern the PPS. At this time, the PPSs are almost evenly split between these two models. For PPSs that formed Newcos, their first compliance challenge was to build a compliance program from the ground up that satisfies the requirements set by New York State regulations and the New York State Office of Medicaid Inspector General (OMIG), including hiring a compliance officer shortly after incorporating when most had no employment infrastructure or policies.[5] Hospital-based PPSs could rely on their existing compliance infrastructure, but had to determine how that would be revised to encompass hundreds of participating entities for DSRIP activities.

OMIG provided webinars and a guidance statement for PPS Leads regarding compliance.[6] The guidance

statement, issued first in April 2015 and then revised in September 2015 (Guidance Statement), advised PPS Leads that they must implement the required eight compliance program elements as applicable to PPS activities.[7] Significantly, OMIG underscored that while compliance programs by PPS Leads must cover issues posed by DSRIP, PPS Leads have no responsibility for overseeing or managing the compliance programs of participating providers in their own operations and services. This principle should run throughout PPS compliance programs and policies; training, reporting, monitoring, and activity to address compliance concerns should focus exclusively on issues posed by PPS operations, PPS projects, and DSRIP activities. This dividing line is critical to both PPS Leads and to participating providers; PPS Leads are not positioned to nor should they want to assume compliance oversight for hundreds of providers. For their part, participating providers and social service organizations will want to maintain their autonomy and the attorney–client privilege as they address internal compliance matters.

With respect to training, OMIG advised that PPS Leads are responsible for compliance training and education for all affected employees, governing body members, and executives throughout the PPS.[8] PPS Leads are not required to provide training directly; they can offer materials or webinars, but must track that training has occurred. For PPS Leads and participating providers, it will be important to determine who should be trained, rather than require blanket training that will not be relevant to workforce members who are not directly involved in a DSRIP project. OMIG advised that the obligation to participate in the PPS compliance program should be reflected in a contractual agreement; the primary agreements between participating organizations and PPS Leads (Participation Agreements) generally include this obligation.

OMIG guidance has stressed that PPS Leads will be responsible for any false data or statements that serve as the basis for a Medicaid payment, which may be deemed fraud and subject to repayment.[9] For this reason, many of the Participation Agreements spell out the obligation of organizations to assure the accuracy of data they submit related to performance and other areas that will be the basis for payment. In a webinar on February 26, 2015, devoted to DSRIP, OMIG asserted as well that PPS Leads would be held responsible for tracking the expenditure of funds by participating providers.[10] In the face of substantial objections to this oversight role by PPS Leads, the OMIG Guidance Statement clarified that PPS Leads are not responsible for how participating providers use DSRIP funds, but must have adequate processes to track performance, with the caveat that if performance falls short, it may trigger the need for an inquiry by the PPS Lead.

To the extent that PPS Leads must track performance in order to report on each DSRIP project to receive payment, OMIG's revised Guidance Statement does not impose a substantial additional responsibility on PPS Leads. At the same time, performance in achieving PPS project goals, such as integrating primary and behavioral health care and reducing preventable use of the emergency room by mental health and substance abuse patients, may fall short for a wide array of reasons entirely unrelated to how funds were expended. Yet, if OMIG demands an inquiry, it will inevitably turn, at least in part, on the use of Medicaid funds. The OMIG Guidance Statement, however, does implicitly give PPS Leads the leeway to require participating organizations to track the expenditure of funds and maintain records in the event of an inquiry, rather than requiring ongoing reports about fund expenditures and proactively overseeing the expenditures.

If an overpayment of Medicaid funds occurs, OMIG and the New York State Department of Health (NYSDOH) have advised that NYSDOH will initiate a process to recoup the funds from the PPS Lead by deducting the payments from future performance payments to the PPS Lead.[11] PPS Leads are in this regard accountable for the actions of participating organizations for the array of conduct that could lead to an overpayment, including submission of false data, reliance on an excluded individual, and mismanagement of Medicaid funds.

Avoiding Overpayments

DSRIP seeks to extend and accelerate activities already under way in federal and state health reform initiatives: care coordination and care management, expansion of primary care and patient-centered medical homes, and patient education and engagement. Yet, as suggested by Medicaid principles and expressly stated by NYSDOH, PPS Leads cannot pay participating providers for activities already paid for in whole or in part by Medicaid or Medicare. The same logic would apply to avoid the waste of public funds to activities paid for by other payers. While seemly simple, this requirement is complex in practice as PPS Leads seek ways to incentivize and support activities already covered in whole or in part by other sources of funds. One solution, especially for payment for activities such as care management, is to fund additional activities explicitly identified in project agreements with providers that are necessary for project implementation. Such activities might include data collection and reporting, improved information technology connectivity, outreach to other providers or to Medicaid beneficiaries not already engaged in care management, or in the case of physician practices that have already achieved patient-centered medical home status, payment to attain the next level of accreditation.

PPS Leads that serve regions that overlap with another PPS must also assure that participating organizations are not paid twice for services they provide. For many projects, health care providers and social service agencies are paid based on the number of Medicaid beneficiaries to whom they deliver a service, such as the Patient Engagement Project, which entails administering an interview instrument called the patient activation measure (PAM) to beneficiaries. In order to assure that participating organizations are not paid by another PPS for providing the instrument to the same Medicaid beneficiary, and that PPS Leads do not include the same beneficiaries when reporting to DOH for payment purposes, PPS Leads must coordinate with one another, requiring them to share personally identifiable data for thousands of Medicaid beneficiaries.

Applying the Fraud and Abuse Laws to Health System Transformation

Federal and state fraud and abuse laws apply to the activities of PPS Leads in disbursing DSRIP funds and designing and managing projects. The fraud and abuse laws also apply to the arrangements between participating organizations to carry out PPS projects. The applicable laws include the federal and state Stark Law, federal and state anti-kickback laws (AKS) and the Civil Monetary Penalties Law.[12] In contrast to PPSs in which the PPS Lead is a hospital or hospital system, PPS Leads that are Newcos do not deliver health care services, and do not bill Medicare or Medicaid as a provider. Compliance with the fraud and abuse laws is therefore less demanding for Newco PPS Leads than for hospital PPS Leads, but still poses complex issues in the flow of funds for DSRIP projects and performance incentives.

The Stark Law prohibits physicians from referring patients to an entity for designated health services (DHS), such as physical therapy or clinical laboratory tests, if the physician or an immediate family member has a direct or indirect financial relationship (compensation, investment, or ownership interest) with that entity, unless an exception applies.[13] Since Newco PPS Leads do not deliver or bill Medicare or Medicaid for DHS, they do not fall within the definition of "entity" under the Stark Law. Funds provided by Newco PPS Leads to physicians do not establish a direct financial relationship within the meaning of the Stark Law. Nor will the funds create an "indirect" financial relationship under the Stark Law as long as Newco PPS Leads do not pay physicians for project participation based on the volume or value of services that physicians refer to hospitals and other entities that bill for DHS.[14]

Application of the Anti-Kickback Law (AKS) is also distinct for Newco PPS Leads than for providers that bill Medicare or Medicaid for services. The AKS bars remuneration of any kind, directly or indirectly, to induce or in exchange for the referral of patients for goods or services paid for, in whole or in part, by a federal or state health care program. Newco PPS Leads do not deliver goods or services billed to Medicaid and Medicare, nor do participating health care providers in each PPS "refer" patients to Newco PPS Leads within the meaning of the AKS. However, participating providers refer patients to other providers in the PPS, and the referral of patients, if successful in meeting DSRIP performance metrics, such as reduced hospital admissions and use, will lead to higher payments for the PPS and for participating organizations. Fund flow models and performance metrics within PPSs operated by Newco PPS Leads must still be assessed and structured for AKS compliance.

PPS Leads that operate within the existing corporate structure of a hospital are "entities" within the meaning of the Stark Law. Physicians may refer patients to the hospital for services that are DHS, requiring that the funds provided by the PPS fit a Stark Law exception.[15] Hospital-led PPSs also disburse DSRIP funds to providers across the continuum of care for DSRIP implementation and performance, including physicians, nursing homes and FQHCs, all of which may refer patients to the hospital. The AKS therefore applies in a more conventional way to the payments by hospital-led PPSs, in contrast to payments by Newco PPS Leads, with implications for both the PPS Leads and participating organizations—the AKS prohibition and associated civil and criminal penalties apply equally to entities that offer and those that receive remuneration to induce or in exchange for referrals.

Conduct that falls within a safe harbor delineated by the AKS has the advantage of a presumption that the conduct does not violate the AKS; conduct outside of a safe harbor may still comply with the AKS, but is not presumed to do so. The personal services and management contract safe harbor as well as other AKS safe harbors, like many exceptions to the Stark Law, require that compensation be set in advance and be at fair market value (FMV). FMV is a challenging benchmark for PPS payments related to network and project development activities. For example, the initial tasks for many DSRIP projects entail outreach to other providers, entering into affiliation agreements, and implementing care protocols. Moreover, in order to succeed, PPS Leads must align payments to participating providers with the incentive payments they receive from the State, relying on performance-based payments that often cannot be set in advance, although the methodology for performance can be specified in advance as part of fund flow plans and project metrics. Other payments, such as the payments that PPS Leads will make to hospitals for lost revenue in

accordance with DSRIP, fall entirely outside the framework contemplated by the fraud and abuse laws.

For all PPS Leads, AKS compliance is complicated by the fact that the goals for certain DSRIP projects, and the overarching goal of reducing preventable hospital admissions and use by 25%, create a tension with the AKS. By seeking a significant shift in patient volume from the inpatient to outpatient settings, DSRIP and other health reform initiatives seek to change patient referral patterns and incentivize referral practices. For example, the DSRIP Emergency Department (ED) Care Triage Project (Project 2.b.iii) funds PPSs to engage participating EDs to reduce preventable ED admissions and refer patients to primary care practices, when medically appropriate. The most direct metric for project performance, and corresponding payment structure, would be payment to EDs based on the number of patients they refer to a primary care practice. Indeed, that is precisely the metric used by DOH for purposes of determining patient engagement for performance payments to PPSs related to speed and scale of project implementation.[16] Yet, EDs refer patients to primary care practices for services paid for by Medicaid and Medicare. Payment for the referrals would fly in the face of the AKS proscription against remuneration to induce referrals for services reimbursed by a federal or state health care program. The AKS does not, however, preclude all payment or incentives for projects that seek to change referral patterns. It requires, however, that PPS Leads and participating providers, as they structure and evaluate payments and performance metrics, distinguish between paying for services that can result in a referral, such as counseling or enhanced data exchange, and paying for the referral itself or payment based on the volume of referrals.

DSRIP performance incentives must also comply with the Civil Monetary Penalties Law (CMP). Among other prohibitions, the CMP bars any hospital from knowingly making a payment, directly or indirectly, to a physician as an inducement to reduce or limit medically necessary services.[17] Until 2015, the CMP barred payments that could induce even medically unnecessary services, except for payments in the context of managed care plans. The CMP was amended in 2015 to narrow its scope to "medically necessary" services to permit incentives aligned with federal and state health reform.[18] This is a hugely important amendment for DSRIP, with its primary goal of reducing unnecessary hospital admissions and use by 25%. By its terms, the CMP applies solely to incentives by hospitals to physicians, but withholding medically necessary services poses a host of risks, including malpractice liability and regulatory enforcement, which means that both hospital-led and Newco-led PPSs should address this risk more broadly as they craft project metrics and performance incentives. For example, a performance metric based solely on reduction in referrals to hospitals and ED visits, without a focus on quality of care or the services provided, will reward a decrease in medically necessary ED visits as well as medically unnecessary visits.

Seeking Safeguards: OIG Advisory Opinions on Gainsharing and Pay-for-Performance

No AKS safe harbor exists for performance incentives that would apply to many of the goals that PPSs and their participants must attain, including reduction in preventable hospital admissions and creation of an integrated delivery system. In 1999, in a Special Advisory Bulletin, the HHS Office of Medicaid Inspector General (OIG) advised that arrangements by which hospitals share cost savings with physicians (generally referred to as gainsharing) would violate the CMP, pointing to the strict prohibition in the statute as well as concerns about the quality of care and potential for fraud and abuse.[19] Notably, the OIG stated that a payment need not lead to an actual reduction in treatment to violate the CMP, as long as the hospital knows that it may influence physicians to limit medical services to their patients. Nonetheless, starting in 2001, the OIG issued a series of favorable opinions of gainsharing arrangements addressing both the CMP and AKS, and two favorable opinions of pay-for-performance arrangements between hospitals and physicians for compensation based on quality metrics and cost savings.[20]

The favorable OIG gainsharing and pay-for-performance opinions found that while the arrangements implicated the AKS and CMP, sufficient safeguards were in place to reduce the risks posed. Notably, in general, the Advisory Opinions address gainsharing arrangements for surgical procedures, such as cardiac catherization, that rely on highly specific clinical protocols and cost-reduction attained through savings related to product standardization, reduced waste of medical supplies and similar cost-saving measures. While not a good fit for many DSRIP projects that target cost savings through broader goals, such as improved care coordination, the Advisory Opinions identify useful factors for consideration as payments are designed for DSRIP and other state and federal reform initiatives.

In considering the risks to CMP compliance and the potential impact on the quality of care for patients, the OIG Advisory Opinions identified certain common elements of the arrangements that supported the decision not to impose sanctions. Among other factors, the OIG Advisory Opinions pointed to the following:

- Credible support that the initiative will improve quality and is unlikely to have adverse effects;

- Specificity of quality measures to assure that the focus is quality, not cost;
- Specific cost-saving opportunities identified based on analysis of historical practices by physicians;
- Hospital committee will monitor quality targets to protect against inappropriate reduction in patient care;
- Incentives are transparent, including written disclosure to patients;
- An agreement in writing for longer than one year; and
- Incentives to physicians are capped and based on aggregate performance, not based on cost savings attained by physicians individually.

The Advisory Opinions also shed light on safeguards to reduce the risks of an AKS violation. In addition to some of the safeguards noted above, the OIG considered the fact that for pay-for-performance arrangements: (i) payments were at FMV; (ii) compensation did not vary with the volume of patients treated; and (iii) participation was open to all existing members of the medical staff.[21]

Certain elements identified as safeguards by the OIG, including reliance on written agreements, implementation of national standards for quality, caps on incentives to physicians, and baseline performance to assess improvement, lend themselves well to DSRIP projects. In addition, given the strong focus of DSRIP on reducing cost and preventable hospital use and admissions as well as the sharp shift in incentives to support this change in the last three years of the program, PPS Leads and participating providers should adopt safeguards to reduce the risk of a CMP violation.

Stepping back from the specific elements of the AKS safe harbors and the safeguards identified by the OIG Advisory Opinions, DSRIP provides additional safeguards that address the underlying concerns of the AKS and CMP: (i) increased costs to federal and state health care programs due to inappropriate referrals; (ii) disguised payments for referrals; (iii) reduction in the quality of care; (iv) incentives to care for only the healthiest patients; and (v) reduction in medically necessary services.

DSRIP seeks to achieve the triple aim of reduced cost, improved quality, and population health management. With respect to overutilization, DSRIP aims to dramatically reduce the cost of care for the Medicaid program, by shifting from more costly, preventable treatment in the inpatient setting to outpatient care and increasing access to primary care. DSRIP projects are designed to recruit and manage the Medicaid beneficiaries who are hardest and most costly to treat, including patients with substance abuse and mental health conditions. PPS Leads must create transparent fund flow plans that will guide payments to participating organizations for projects delineated by NYSDOH. NYSDOH has approved the detailed implementation plans submitted by each PPS Lead, and will evaluate performance on a quarterly basis. PPS Leads are required to use evidence-based protocols for project implementation and report to NYSDOH on standardized metrics that will be publicly posted. In short, while the exceptional level of NYSDOH oversight and prescriptive DSRIP requirements are a burden for PPS Leads and participants alike, the unusual degree of state involvement provides significant safeguards likely to be considered by the OIG as it evaluates gainsharing and pay-for-performance incentives.[22]

Conclusion

DSRIP programs in varying forms have been implemented in eight states, with negotiations ongoing between CMS and other states to initiate the program. Lessons learned and the challenges confronted in New York State offer valuable insight for national policy and practice. OIG Advisory Opinions on gainsharing and performance payments, as well as the 2014 Proposed Rule to expand AKS safe harbors and permissible payments under the CMP to Medicare and Medicaid beneficiaries, reflect mounting recognition of the need to align application of the fraud and abuse laws with federal and state health reform.[23] Federal and state governments in their roles as policy makers and regulators need to close that gap. CMS and the OIG adopted waivers for the Shared Savings Program and most recently for the bundled payment program for joint replacement.

They should do the same for DSRIP programs, crafting waivers of the fraud and abuse laws to support the novel payments that lead organizations must make for infrastructure development, project implementation, and performance payments.[24] Even if consistent with aims set by state policy, metrics for DSRIP performance, as established by state agencies, by lead entities, and by participating organizations must be devised so they are compatible with the fraud and abuse laws. Finally, given the converging shift in incentives by public and private payers to reduce utilization, training should be an essential element of program implementation so that the incentives, as translated in the direct interaction with patients, are not misunderstood or misapplied.

Endnotes

1. Deborah Bachrach, William Bernstein, Jared Augenstein, Mindy Lipson & Reni Ellis, *Implementing New York's DSRIP Program: Implications for Medicaid Payment and Delivery System Reform*, THE COMMONWEALTH FUND (April 2016), http://www.commonwealthfund.org/~/media/files/publications/fund-report/2016/apr/1871_bachrach_implementing_new_york_dsrip_v4.pdf?la=en. Other states currently implementing some form of DSRIP program are: Alabama, California, Kansas, Massachusetts, New Hampshire, New Jersey and Texas.
2. For extensive information about the 25 performing provider systems (PPSs) approved by the New York State Department of Health (NYSDOH) and DSRIP projects, milestones, funding, regulatory requirements and mandated elements for the integrated delivery systems PPSs must build, among other information, *see Delivery System Reform Incentive Payment (DSRIP) Program*, NEW YORK STATE DEPT. OF HEALTH, http://www.health.ny.gov/health_care/medicaid/redesign/dsrip/ (last visited May 26, 2016).
3. Medicare Program; Final Waivers in Connection With the Shared Savings Program, 76 Fed. Reg. 67992 (Nov. 2, 2011).
4. *See id.*; Federal Trade Commission and United States Department of Justice, Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 67026 (Oct. 28, 2011); I.R.S. Notice 2011-20.
5. 18 N.Y.C.R.R. Part 521.
6. Delivery System Reform Incentive Payment (DSRIP) Program, *DSRIP Compliance Guidance 2015-01—Revised, Special Considerations for Performing Provider System (PPS) Leads' Compliance Programs*, NYS OFFICE OF MEDICAID INSPECTOR GENERAL (Sep. 1, 2015), https://www.omig.ny.gov/images/stories/compliance_alerts/20150901_DSRIP_CompGuidance_2015-01_Rev.pdf ("Guidance Statement"); *OMIG Webinar Materials: OMIG Call Recording*, NEW YORK STATE DEPT. OF HEALTH (Feb. 26, 2015), https://www.health.ny.gov/health_care/medicaid/redesign/dsrip/webinars_presentations.htm; *OMIG Webinar Materials: OMIG Call Recording*, NEW YORK STATE DEPT. OF HEALTH (Apr. 7, 2015), https://www.health.ny.gov/health_care/medicaid/redesign/dsrip/webinars_presentations.htm.
7. *See* Guidance Statement, *supra* note 6.
8. *See* Delivery System Reform Incentive Payment (DSRIP) Program, *DSRIP Compliance Guidance 2015-02, Frequently Asked Questions by Performing Provider System (PPS) Leads Relative to Compliance Programs*, NEW YORK STATE OFFICE OF MEDICAID INSPECTOR GENERAL AND NEW YORK STATE DEPARTMENT OF HEALTH (July 15, 2015), https://www.omig.ny.gov/images/stories/compliance_alerts/20150715_dsrip_faqs.pdf.
9. *Special Considerations for Performing Provider System (PPS) Leads' Compliance Programs, supra* note 6.
10. *OMIG Webinar: PPS Compliance Program, supra* note 6.
11. *DSRIP Program FAQs, supra* note 8.
12. Federal Stark Law, 42 U.S.C. § 1395nn; NYS Prohibition on Provider Referrals Law (also referred to as the State Stark Law) NYS Public Health Law, § 238-a; Federal Anti-Kickback Law, 42 U.S.C. § 1320a-7b(b); NYS Anti-Kickback Law, N.Y. Educ. Law § 6530(18); Civil Monetary Penalties Law, Social Security Act § 1128, 42 U.S.C. § 1320a-7a.
13. 42 U.S.C. §§ 1395nn(a)1-2.
14. 42 U.S.C. § 1395nn(a)2.
15. For Stark Law exceptions *see* 42 U.S.C. §§ 1395nn(b)-(e).
16. *Revised DSRIP Actively Engaged: Project Specific Definitions and Clarifying Information*, NEW YORK STATE DEPARTMENT OF HEALTH, 11 (Oct. 28, 2015), https://www.health.ny.gov/health_care/medicaid/redesign/dsrip/docs/2015-10-28_actively_engaged_definitions.pdf.
17. Civil Monetary Penalties Law, Social Security Act § 1128A, 42 U.S.C. § 1320a-7a.
18. Medicare Access and CHIP Reauthorization Act of 2015 § 512, Pub. L. No. 114-10, 129 Stat. 87.
19. *Gainsharing Arrangements and Civil Monetary Penalties for Hospital Payments to Reduce or Limit Services to Beneficiaries*, OFFICE OF THE INSPECTOR GENERAL (July 1999), http://oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm.
20. *See, e.g.*, OIG, Advisory Opinion No. 07-22 (Jan. 14, 2008); OIG, Advisory Opinion No. 06-22 (Nov. 16, 2006); OIG, Advisory Opinion No. 08-16 (Oct. 7, 2008); OIG, Advisory Opinion No. 12-22 (Jan. 7, 2013). In 2008, CMS issued a proposed rule to create a new exception for gainsharing under the Stark Law. 73 Fed. Reg. 38502 (July 7, 2008). The rule has not yet been adopted in final form.
21. OIG, Advisory Opinion Nos. 08-16, 12-22.
22. *See* discussion of safeguards in proposed regulations amending safe harbors to the AKS and exceptions to the CMP definition of remuneration, 79 Fed. Reg. 59726 (Oct. 3, 2014).
23. 79 Fed. Reg 59725 (Oct. 3, 2014).
24. *See* waivers granted by CMS for other innovation programs, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html.

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The SHIN-NY Enables PPSs and Other Health Care Systems to Achieve Clinical Integration

By Jonathan Karmel

Introduction

Health care providers and systems that are implementing New York's delivery system reform efforts, including Health Homes and Performing Provider Systems (PPSs), require access to Protected Health Information (PHI) in order to improve clinical and population health management and reduce costs.

Regional Health Information Organizations (RHIOs) in New York State now have clear legal authority to allow access to patient information in the Statewide Health Information Network for New York (SHIN-NY). Health system participants will be able to access both clinical and claims data through a secure, internet-based portal. This article explains what information will be available, who may access the records, when patient consent is needed and how patients can monitor who accesses their information. This article also provides a legal analysis of some of the ways that the SHIN-NY is being used to support public health and health system integration efforts. The SHIN-NY is a critical tool for delivery system reform, which will make it possible for public and private health plans to implement value-based payment programs to improve clinical and population health management, and reduce costs.

RHIOs were established in New York with substantial State subsidies under the Health Care Efficiency and Affordability Law for New Yorkers (HEAL NY) Capital Grant Program.[1] New York now has eight RHIOs, which are not-for-profit organizations that facilitate the standards-based exchange of information derived from electronic health records (EHRs). Under grant contracts, the New York State Department of Health (DOH) has contractually obligated them to comply with SHIN-NY policy standards.[2] Under the SHIN-NY regulation adopted this year, the RHIOs are called "qualified entities" (QEs),[3] and the SHIN-NY policy standards are referred to as SHIN-NY policy guidance.[4] There is SHIN-NY policy guidance, revised in March 2016, for: (1) organizational characteristics of QEs; (2) QE minimum service/technical requirements; (3) privacy and security; (4) monitoring/oversight and enforcement; and (5) QE certification.[5] DOH has also contracted with a ninth not-for-profit organization called the New York eHealth Collaborative (NYeC)[6] to facilitate a statewide collaboration process.[7] DOH also contracted with NYeC to create a statewide patient record look-up, the statewide electronic infrastructure that connects the eight QEs together and allows access to medical records from any QE through any other QE.[8]

In order to transition the SHIN-NY from a grant-funded network of not-for-profit organizations to a public utility serving New York State's entire health care system, DOH created the Bureau of Health Information Exchange within its Office of Quality and Patient Safety. The SHIN-NY regulation was proposed on November 4, 2015[9] and became final and effective on March 9, 2016.[10] Under the regulation, general hospitals that qualify for the federal "meaningful use" incentives[11] must connect to the SHIN-NY within one year, and all other such health care facilities regulated by DOH must connect to the SHIN-NY within two years.[12]

New York State Regulation of Health Information Systems

In 2010, DOH was given legislative authority to regulate the SHIN-NY.[13] In 2014, DOH was required to convene a workgroup to evaluate the State's health information technology and systems, including the SHIN-NY.[14] The members of the workgroup include the chair of the Senate health committee and the chair of the Assembly health committee.[15] The workgroup was required to submit an interim report in 2014,[16] and a final report in 2015.[17] DOH's charge from the legislature is to enable widespread, non-duplicative interoperability among health information systems, including the State's network of QEs[18] and health care claims databases,[19] and to support New York Medicaid program delivery system reform efforts, including Health Homes and the Delivery System Reform Incentive Payment program (DSRIP).[20]

Consistent with the recommendations of the statutorily-created workgroup, which includes members of the Legislature, DOH has added a new Chapter IV to the State's health regulations titled "Health Information Systems," and a new Part 300, which is the SHIN-NY regulation.

What Medical Records Are Available Using the SHIN-NY

The SHIN-NY regulation requires general hospitals (including outpatient departments), ambulatory surgery centers, diagnostic and treatment centers, clinics, nursing homes, health maintenance organizations (as health care providers), home care services agencies and hospice programs to connect to the SHIN-NY.[21] Many other health care providers, including mental hygiene facilities and private practices, are also connecting to the SHIN-NY.

Health care providers connect to the SHIN-NY by entering into a participation agreement with a QE.[22] Under the participation agreement, the QE is the HIPAA "business associate" of the QE participants.[23] Health care providers who are QE participants may, but are not be required to, provide patients the option to withhold patient information from the SHIN-NY.[24] The medical records of patients who are not given that option, as well as those who are given the option to withhold information but choose to provide the information, will be available through the SHIN-NY.[25] The SHIN-NY is an "all or nothing" system, in the sense that when a health system participant is able to access patient information through a QE, the participant is able to access all of the patient's information that is accessible through a QE.

Health Care Provider Access to Patient Information Using the SHIN-NY

1. QE Participant disclosing patient records to another QE Participant in a "One-to-One Exchange."

In the 20th Century world of paper medical records, a health care provider was always able to hire a company to warehouse medical records, or to utilize a courier service to transport medical records, without getting consent from patients to make it possible for the warehouse or the courier to see the patient information.[26] Traditionally, this was neither permitted nor prohibited by statute; it took place under the common law of agency. In the electronic environment, QEs can also be used to provide the service of transmitting patient information on behalf the health care providers that are QE participants.[27] Here, the QE is simply performing the service of transmitting patient information from one QE participant to others in a way that mirrors a paper-based exchange.

For example, a QE participant may use a QE to order a clinical laboratory test from a clinical laboratory that is also a QE participant, and the clinical laboratory can transmit the results back to the ordering provider. Here, the QE is just acting as a health IT vendor, and the SHIN-NY regulation does not require any additional type of patient consent. Another example would be where the patient of one QE participant signs a consent form that complies with applicable laws, such as the DOH-5032 form.[28] This type of one-to-one exchange continues to be governed by the extensive, pre-existing rules that were created for paper medical records. The SHIN-NY regulation does not require a special SHIN-NY consent. Just like an IT vendor that provides an emailing or fax-type service, the QE is simply facilitating the transmission of the medical records from one QE participant to other QE participants.[29] The exchange is understood and predictable to a patient.[30]

The kinds of exchanges that are "understood and predictable" to patients are likely to change over time as the public becomes more aware of the SHIN-NY and the evolving role of health plans in a reimbursement system that is value-based rather than fee-for-service. Enrollees will become more aware of the way that they have agreed to allow their information to be exchanged under enrollment agreements (or the terms contained in public insurance applications). In addition, one QE participant could also engage in a one-to-one exchange with another QE participant who is a HIPAA-business associate or is part of the same HIPAA-Organized Health Care Arrangement.[31]

2. A QE Participant accessing all of the patient's records available through the SHIN-NY.

The SHIN-NY regulation provides additional rules that must be followed before a QE may allow a QE participant to access all of the patient's records that are available through the SHIN-NY. Health care providers may access patient information without patient authorization in an emergency.[32] In general, however, patient information may only be accessed from the SHIN-NY by a health care provider treating the patient with the written consent of the patient.[33] Each QE must use the standardized SHIN-NY consent form or one that is "substantially similar."[34] All eight QEs have adopted substantially similar consent forms.[35]

How Patients Can Monitor Who Accesses Their Medical Records

Both HIPAA and State law give patients a right, upon written request, to access their own clinical records from a health care provider as well as information regarding the health care provider's disclosure of patient information to third parties.[36] The SHIN-NY regulation requires QEs to provide a patient with access to patient information maintained by the QE as well as the identities of any QE participants that have accessed the patient information.[37] In reality, patients may not have much control or knowledge about consent to electronic health information exchange on the "front end," unless the patients have control over which providers they see and/or the patients pay for their own care out of pocket. On the other hand, the SHIN-NY gives patients a much greater ability to see who has accessed their information on the "back end" than a paper-based medical records system. For the average patient, consent may actually be less important than the belief that the only people who have accessed his or her information are trustworthy health system participants who have a demonstrable need to access their information.[38]

Public Health Authority Access to Patient Information Using the SHIN-NY

DOH, the New York City Department of Health and Mental Hygiene and county health departments are accessing patient information from the SHIN-NY as public health authorities. QEs may allow public health authorities to access patient information without consent for public health activities authorized by law.[39] For example, public health officers may access patient information "to investigate cases of communicable disease, to ascertain sources of infection, to seek out contacts and to take other steps to reduce morbidity and mortality."[40] The SHIN-NY will also help in DOH's efforts to end the AIDS epidemic by facilitating "patient linkage and retention in care."[41] Government access is limited to the type of access that the government has always had to paper medical records and is subject to audit in the same way as access by private entities.[42] The SHIN-NY will allow the government to access patient information for public health activities more effectively and efficiently and at lower taxpayer cost.

New York Health Delivery System Reform Efforts

1. Sharing of Medicaid Data

Under federal law, the Medicaid program may only use information concerning applicants and recipients for purposes directly related to administration of the Medicaid program.[43] In order to safeguard the privacy and security of Medicaid data, the Medicaid program requires users of Medicaid data to complete a data exchange application and agreement (DEAA).[44]

2. Health Homes

A Medicaid Health Homes lead is required to enter into a DEAA with the Medicaid program.[45] Medicaid beneficiary enrollment in the Health Homes program is voluntary, and Medicaid beneficiaries who choose not to enroll in a Health Homes program can opt out of getting Health Home services. With the consent of the Medicaid beneficiary, the Health Home lead may share Medicaid data with Health Home partners and may access the beneficiary's medical records from the SHIN-NY.[46]

3. DSRIP

In the case of DSRIP,[47] Medicaid beneficiaries are assigned to a Performing Provider System (PPS) and are given the option of not having their Medicaid data shared with the PPS lead and partners.[48] A PPS lead is required to enter into a DEAA with the Medicaid program.[49] The Medicaid program is also in the process of developing a DEAA to allow QEs to receive Medicaid data in order to provide services to PPSs.

PPS participants may access a Medicaid beneficiary's patient information using a QE. As explained above, one PPS participant could disclose information to another PPS participant in a one-to-one exchange.[50] This could take place if the Medicaid beneficiary has given consent for the first PPS participant to disclose patient information to the second PPS participant. Another possibility is that the PPS lead is a HIPAA business associate of the PPS participant. As a business associate, the PPS lead is, on behalf of the PPS participant, receiving and using patient information to fulfill the requirements of the DSRIP program so that the PPS participant will be able to receive the DSRIP incentive payments. It could also be the case that both PPS participants are part of the same Organized Health Care Arrangement under HIPAA, and the HIPAA Notice of Privacy Practices of each PPS participant indicates that clinical data may be shared between them.[51]

PPS participants may also access patient information from QEs as QE participants using a standardized SHIN-NY consent form under the privacy and security SHIN-NY policy guidance, which allows QE participants to access all of the patient's information that is available in the SHIN-NY.

It is worth noting that while the DSRIP program utilizes PPSs, it is anticipated that in the future payers will increasingly be implementing value-based payment systems that rely on Accountable Care Organizations (ACOs).[52] Whether or not the ACOs are also PPSs, the ACOs will be able to use the SHIN-NY in a manner similar to the way the PPSs are using the SHIN-NY.

Legal Exposure

Health system participants who disclose or access health information need to consider their risk of liability in the event of a privacy or security breach. The privacy and security SHIN-NY policy guidance under 10 N.Y.C.R.R. § 300.3(b)(1) defines disclosure in a "One-to-One Exchange," access with "Affirmative Consent," and access without consent using "Break the Glass."[53] A one-to-one exchange is similar to a traditional disclosure of paper medical records. The QE is relying upon a representation by the disclosing party that the disclosing party is legally authorized to make the disclosure, and the disclosing party would bear responsibility for a privacy breach for asking a QE to facilitate an unauthorized disclosure. When a QE participant accesses health information from the SHIN-NY with break the glass, the QE participant breaking the glass is primarily responsible for a privacy breach if that QE participant is not authorized to access the information. When a QE participant accesses health information from the SHIN-NY with affirmative consent, in theory there cannot be an unauthorized disclosure, but the QE is primarily responsible for maintaining docu-

mentation that consent has been obtained.[54] For all three types of electronic health information exchange being facilitated by the QE, the QE is primarily responsible for securing the data in transit.

In evaluating exposure, it is important to consider whether a private right of action exists,[55] or whether the only exposure comes in the form of government enforcement action. If the only exposure is possible government enforcement action, then it is important to consider whether policies and procedures are consistent with federal and State laws, regulations and guidance documents. Since privacy and security breaches are to some extent inevitable, it is also important to evaluate the extent to which any liability can be mitigated with insurance coverage. In addition to these tangible monetary considerations, most of the health care participants will also be highly motivated to maintain a reputation of trustworthiness.

Conclusion

The laws governing consent to disclose patient information are complex. The rules can vary depending on who is disclosing and accessing the information, the type of information and the purpose of the exchange, whether the information is considered a medical record or claims data and whether or not federal laws are applicable. In addition, the common law of agency may apply to disclosures to contractors. The new Part 300 of New York's health regulations defines the SHIN-NY as "the technical infrastructure and the *supportive policies and agreements* that make possible the electronic exchange of clinical information among qualified entities and qualified entity participants for authorized purposes to improve the quality, coordination and efficiency of patient care, reduce medical errors and carry out public health and health oversight activities, while protecting patient privacy and ensuring data security [emphasis supplied]."[56] Among other things, these policies and agreements require QEs to maintain an audit log of access to patient information by users of the SHIN-NY. Regardless of whether the various applicable laws require consent, or give patients the opportunity to opt out of allowing exchange of patient information, it is really the enforcement of these policies and agreements, and the ability of patients and others to monitor these audit logs, that will safeguard the privacy and security of the information that is exchanged using the SHIN-NY.

As more health care providers, health plans and government agencies connect to the SHIN-NY, there will be additional opportunities to increase the use of health information technology to improve clinical care, population health and public health. The SHIN-NY is an essential part of New York's transformation of the health delivery and payment systems. The SHIN-NY is a health information system that will make health system integration possible.

Endnotes

1. PHL §2818. HEAL NY Phases 1, 5, 10, 17 and 22 were for health information technology, and then subsequent appropriations for the SHIN-NY were included in the State Budgets: L. 2014, ch. 54, L. 2015, ch. 54, and L. 2016, ch. 55.
2. SHIN-NY policy standards were incorporated by reference into the SHIN-NY regulation that was proposed by DOH on September 3, 2014. *NYS Register*, September 3, 2014, pp. 9-11.
3. 10 NYCRR §300.1(b).
4. 10 NYCRR §300.3(f).
5. The SHIN-NY policy guidance is available here: http://www.health.ny.gov/technology/regulations/shin-ny/. Policy guidance is not a "rule" under SAPA §102(2)(a). Nevertheless, DOH's grant contracts with the QEs continue to contractually obligate QEs to follow the SHIN-NY policy guidance.
6. On September 9, 2009, Governor David A. Paterson made NYeC, a not-for-profit organization, the "state-designated entity" to receive a federal grant that was available to states to promote health information technology. See 42 U.S.C. §300jj-33.
7. DOH created the SHIN-NY policy guidance under the statewide collaboration process. 10 NYCRR §§300.1(e), 300.3. The statewide collaboration process includes meetings of the SHIN-NY Policy Committee and the Business & Operations Committee (BOC), http://www.nyehealth.org/shin-ny/policy-governance/. DOH will continue to update SHIN-NY policy guidance based on recommendations from these committees.
8. See 10 NYCRR §300.4(a)(2).
9. *NYS Register*, November 4, 2015, pp. 20-21.
10. *NYS Register*, March 9, 2016, pp. 32-34.
11. Under a federal law called the Health Information Technology for Economic and Clinical Health Act (HITECH), the federal government is providing Medicare and Medicaid incentive payments to health care providers that adopt "meaningful use" of certified EHR technology. HITECH is within the American Recovery and Reinvestment Act of 2009 (ARRA, P.L. 111-542). HITECH is ARRA Division A, Title XIII-Health Information Technology and ARRA Division B, Title IV-Medicare and Medicaid Health Information Technology. See 42 CFR Part 495.
12. 10 NYCRR §300.6(a).
13. L. 2010, ch. 58, Pt. A, §11.
14. L. 2014, ch. 60, Pt. A, §16.
15. PHL §206(18-a)(c).
16. PHL §206(18-a)(b)(iii). The Interim Report is posted here: http://www.health.ny.gov/technology/innovation_plan_initiative/docs/2014-12_hit_interim_report.pdf.
17. PHL §206(18-a)(b)(iv). The Final Report is posted here: https://www.health.ny.gov/technology/innovation_plan_initiative/docs/hit_workgroup_final_report.pdf.
18. DOH has authority to regulate "organizations covered by 42 U.S.C. §17938." PHL §206(18-a)(d). 42 U.S.C. §17938 is a provision of HITECH regarding organizations such as health information exchange organizations (HIEs) or RHIOs. Thus, the SHIN-NY regulation codifies the rules for such organizations, which are referred to as QEs.

19. DOH's Office of Health Insurance Programs maintains Medicaid claims in the Medicaid Management Information System. In addition, PHL §2816 and PHL §206(18-a) give DOH authority to create an all-payer database (APD). In the future, DOH will establish another health information system regulation for the APD.

20. See 42 U.S.C. §1396w-4; Social Services Law §365l (health homes); 42 U.S.C. §1315 (authority for federal CMS Social Security Act section 1115 DSRIP waivers); the waiver itself can be found here: http://www.health.ny.gov/health_care/medicaid/redesign/dsrip/cms_official_docs.htm#bottom.

21. 10 NYCRR §300.6(a).

22. NYeC also has a qualified entity participation agreement with each QE, sometimes referred to as the QEPA (pronounced "queepa").

23. HIPAA allows health care providers to disclose protected health information to business associates without a HIPAA authorization. New York has always also allowed health care providers to contract with companies to store or transport medical records without patient consent, but the SHIN-NY regulation makes clear that this practice does not violate State law. 10 NYCRR §300.5(a). In the case of QE participants that are governed by the federal regulations in 42 CFR Part 2 for substance use disorder patient records, the QE is also the "qualified service organization" of the QE participant. In 2010, the federal Substance Abuse and Mental Health Services Administration (SAMHSA) issued guidance (which was supplemented on December 8, 2011) explaining that under 42 CFR Part 2, a RHIO participant may disclose substance use disorder patient records to a RHIO without patient consent provided that the RHIO enters into an appropriate Qualified Service Organization agreement with the RHIO participant. http://www.samhsa.gov/sites/default/files/faqs-applying-confidentiality-regulations-to-hie.pdf; FAQs, December 8, 2011; 42 CFR §2.12(c)(4); see also 81 Fed. Reg. 6988-7024, February 9, 2016 (proposed rule amending 42 CFR Part 2).

24. 10 NYCRR §300.5(a). DOH anticipates that some health care providers, such as behavioral health and abortion providers, and others whose patients have an especially high desire for confidentiality, will exercise this option. Nevertheless, even those providers are required to give their patients who do consent the opportunity to make their medical records available using the SHIN-NY. Under federal law, a HIPAA-covered entity must honor a patient's request to restrict the disclosure to a health plan of information that pertains solely to a health care item or service for which the health care provider involved has been paid out of pocket in full. 42 U.S.C. §17935; 45 CFR §164.522(a)(1)(vi).

25. QEs provide the service of making medical records available through the SHIN-NY. Making it possible for QEs to provide this service is sometimes called "uploading" the records to the SHIN-NY.

26. For example, many health care providers used CitiStorage to warehouse medical records without getting any consent from their patients to disclose patient information to CitiStorage. On January 31, 2015, a fire at the CitiStorage warehouse resulted in medical records being strewn around the Williamsburg neighborhood of Brooklyn. *Fire at a Brooklyn Warehouse Puts Private Lives on Display*, N.Y. Times, Feb. 2, 2015, at A14. It is also common for health care providers to use FedEx to ship medical records to another health care provider without getting consent from the patient to disclose the records to the FedEx courier.

27. 45 CFR §164.502(e); 10 NYCRR §§ 300.4(a)(5); 300.5(a).

28. http://www.health.ny.gov/forms/doh-5032.pdf.

29. The authorization would be "prior consent" under 10 NYCRR §300.5(c)(1), and this would be a "one-to-one exchange" according to the privacy and security SHIN-NY policy guidance under 10 NYCRR §300.3(b)(1).

30. The term "One-to-One Exchange" is defined in the privacy and security SHIN-NY policy guidance under 10 NYCRR §300.3(b)(1) as "a disclosure of Protected Health Information by one of the patient's providers or other Participants to one or more other Participants either treating the patient or performing Quality Improvement and/or Care Management activities for such patient with the patient's knowledge and implicit or explicit consent where no records other than those of the Participants jointly providing health care services to the patient are exchanged. A One-to-One Exchange is an electronic transfer of information that is understood and predictable to a patient, because it mirrors a paper-based exchange, such as a referral to a specialist, a discharge summary sent to where the patient is transferred, lab results sent to the Practitioner who ordered them or clinical information sent from a Participant to the patient's health plan for Quality Improvement or Care Management/coordination activities for such patient."

31. See 45 CFR §160.103(*Business associate*) and (*Organized health care arrangement*).

32. 10 NYCRR §300.5(c)(3); *see also* 42 CFR §2.51.

33. 10 NYCRR §300.5(a).

34. Section 1.3 and Appendix A of the privacy and security SHIN-NY policy guidance under 10 NYCRR §300.3(b)(1).

35. Now that the SHIN-NY has been established and participants will be able to access all patient information in the SHIN-NY from any QE using the statewide patient record look-up, it would make sense to develop a single consent form that can be used to access patient information from any of the eight QEs. This will be especially useful for providers that operate statewide, such as facilities operated by the State Office of Mental Health (OMH) or the U.S. Department of Veterans Affairs (VA).

36. 45 CFR §§164.524, 164.528; PHL §18(2) and (6). The federal Department of Health and Human Services proposed, but never finalized, amendments to HIPAA that would amend 45 CFR §164.528 to require HIPAA-covered entities to account for disclosures for treatment, payment and health care operations if such disclosures are through an EHR. 76 Fed. Reg. 31426-31449 (May 31, 2011).

37. 10 NYCRR §300.4(a)(8) and (9); Section 6 of the privacy and security SHINNY policy guidance under 10 NYCRR §300.3(b)(1) requires QEs to maintain audit logs and to give patients access to audit information.

38. *Cf.* Mental Hygiene Law §33.13(c).

39. 10 NYCRR §300.5(c)(2)(ii)(*a*); see also 42 U.S.C. §1320d-7(b); 45 CFR §164.512(b).

40. 10 NYCRR §2.6.

41. PHL §2135.

42. Section 1.2.2 of the privacy and security SHIN-NY policy guidance under 10 NYCRR §300.3(b)(1); DOH Administrative Policy and Procedure Manual (APPM) #302.0.

43. 42 U.S.C. § 1396a(a)(7); 42 CFR Part 431, Subpart F. 42 USC § 1396a(a)(7) was included in Title XIX of the Social Security Act, because it was one of the "standard provisions" that was in other titles of the Social Security Act (see 1965 USCCAN 2014-2015, 2269-2270). After the original Social Security Act was passed in 1935, the elected officials in some states used information concerning applicants and recipients to solicit political support from constituents. For example, from 1936-

1938, Ohio Governor Davey sent social security recipients in Ohio letters indicating that he had increased their benefits and that they and their friends should vote for him. As a result, the Social Security Board recommended an amendment to the law to protect the confidential character of social security information. Altmeyeregis, Arthur J., The Formative Years of Social Security, 1966, pp. 74-79. The reports of the House Committee on Ways and Means and the Senate Committee on Finance contained the same explanation for the provisions to restrict the use of information concerning applicants to purposes directly connected with administration of the plan. "This is designed to prevent the use of such information for political and commercial purposes" (House Rept. 728 on H.R. 6635, 76th Cong., 1st session, 3; Senate Rept. 734 on H.R. 6635, 76th Cong., 1st session, 3).

44. The DEAA is a data use agreement that the Medicaid program requires anyone who uses Medicaid data to sign. When HIPAA went into effect, the DEAA was amended so that it could also meet the requirements for a HIPAA business associate agreement.

45. https://www.health.ny.gov/health_care/medicaid/program/medicaid_health_homes/medicaid_enroll_prov-led_hh_rev.htm#5.

46. See http://www.health.ny.gov/health_care/medicaid/program/medicaid_health_homes/forms/.

47. The New York State Department of Health's current guidance on this topic is contained in "Privacy and Data Sharing within DSRIP JUNE2016.pdf" (attachment to email from doh.sm.delivery.system.reform.incentive.payment.program to PPSs, sent Tuesday, June 14, 2016 at 2:56 p.m.).

48. See https://www.health.ny.gov/health_care/medicaid/redesign/dsrip/consumers/docs/eng_optout_ph2.pdf.

49. See https://www.health.ny.gov/health_care/medicaid/redesign/dsrip/data_security/deaa_addendum.htm.

50. See definition of the term "One-to-One Exchange" in the privacy and security SHIN-NY policy guidance under 10 NYCRR §300.3(b)(1). Here, the Medicaid beneficiary has arguably consented to the disclosure under the terms of the Access NY Health Care health insurance application form (DOH-4220all). See also the SHIN-NY regulation Assessment of Public Comments, pp. 52-54 at http://www.health.ny.gov/regulations/recently_adopted/docs/2016-03-09_shin_ny.pdf. In addition, the Medicaid beneficiary is able to opt out of having Medicaid data shared with a PPS. This is a one-to-one exchange, because there is implicit consent to allow a QE participant to share information with another QE participant for the care management/coordination activities being conducted by the PPS for the patient. It is important to note, however, that the conclusion that this is a one-to-one exchange simply means that that a QE can facilitate the disclosure. The PPS participant disclosing patient information must still make the determination that the disclosure is authorized by law, and could be held liable for an unauthorized disclosure just the same as if the PPS partner were mailing a paper medical record. See, *e.g.*, Education Law §6530(23).

51. See 45 CFR §164.506(c)(5). Special constraints would apply, however, to certain substance use disorder treatment, mental health and HIV-related medical records. See Mental Hygiene Law §33.13(c)(9)(i) and second and third sentences of §33.13(d), as amended by L. 2016, ch. 59, Pt. M, §§1-3.

52. See Public Health Law Article 29-E; 10 NYCRR Part 1003. See also http://www.health.ny.gov/health_care/medicaid/redesign/aco/.

53. QE participants can "break the glass" in case of emergency, as the term implies. But in terms of the technical architecture of the system and legal exposure, access by the government, without the consent of the patient as authorized by law, works the same way.

54. If the QE is reasonably relying on a representation that another party has obtained consent, the other party who made that representation would of course bear responsibility if no consent was in fact obtained.

55. See, *e.g.*, Doe v. Guthrie Clinic, Ltd, 740 F3d 864 (2d Cir 2014).

56. 10 NYCRR §300.1(a).

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Confidentiality and Patient Consent Issues Related to the Sharing of Substance Use Disorder Information with DSRIP and Performing Provider Systems (PPSs)

By Robert A. Kent, Trisha Schell-Guy and Mark S. Boss

OASAS

The New York State Office of Alcoholism and Substance Abuse Services (OASAS) is the single designated state agency responsible for the coordination of state-federal relations in the area of substance use disorder (SUD) services. OASAS oversees one of the nation's largest addiction services systems with nearly 1,600 prevention, treatment and recovery programs. OASAS SUD treatment programs assist about 100,000 people each day and approximately 240,000 individuals every year.

On a daily basis, OASAS staff assist New York State SUD providers in dealing with the practical aspects of disclosing protected information consistent with the requirements of the federal confidentiality regulations, 42 CFR Part 2 (Part 2). In OASAS' experience, these confidentiality regulations in their present form impose no significant impediment to the electronic exchange of confidential protected information. Where exchange systems are developed to incorporate Part 2's requirements within their protocols, there is no reason why SUD treatment information cannot be exchanged and secured in a manner consistent with the confidentiality law.

Often it has been OASAS' experience that providing some education regarding Part 2's basic requirements and recognized best practices for addressing disclosure issues alleviates common misconceptions that Part 2 imposes undue burdens to the exchange of treatment information. Further, assuring familiarity with the requirements of Part 2 early in the design process of any major initiative is critical to ensuring development of a project that facilitates successful exchange of protected health information (PHI) that includes SUD information.

The Federal Confidentiality Law

The Federal alcohol and drug confidentiality law, 42 CFR § 290dd-2, and its implementing regulations, 42 CFR Part 2, impose restrictions upon the disclosure and use of SUD patient records which are maintained in connection with the performance of any federally assisted alcohol and drug abuse program.[1]

The restrictions on disclosure apply to any information disclosed by a Part 2 program that identifies an individual directly or indirectly as having a current or past drug or alcohol problem, or as a participant in a Part 2 program.[2] Under Part 2, a patient is defined as "any individual who has applied for or been given diagnosis or treatment for alcohol or drug abuse at a federally assisted program." Patient-identifying information means any information which identifies an individual, either directly or indirectly, as having received, receiving, or having been referred for, SUD treatment services.[3]

It should be noted that Part 2 only prohibits the unauthorized disclosure of patient-identifying SUD information. Other Protected Health Information (PHI) which does not identify the patient as having received SUD services can be disclosed pursuant to the Health Insurance Portability and Accountability Act (HIPAA).[4] HIPAA does not require a patient's consent to disclose PHI for the purposes of treatment, payment, or health care operations.[5]

Patient Consent

The current state of the law provides clear mechanisms for disclosure of protected information.[6] In general, patient consent is required unless one of the following exceptions applies: a medical emergency, a report of child abuse or neglect, the patient commits a crime on program premises, research activities, program audit/evaluations or a court order. Given the clear exceptions to consent, patients remain the primary decision makers regarding who receives their SUD information, what SUD information is disclosed and the purpose for which their confidential treatment records can be used. The patient's right to make these decisions is equally valid whether such disclosures are to treatment providers, health homes, information exchanges, or any of the intermediary, ancillary entities that participate in today's varied and emerging health care delivery models.

A valid consent form, signed by the patient, accompanied by a statement clearly articulating Part 2's prohibition on redisclosure, remains the best method to protect the confidentiality of the patient's SUD information. Such consent gives the patient maximum control over their protected information, while still allowing that patient to share in the benefits of an integrated health care system.

A Valid Consent to Disclose Patient Identifying Substance Use Disorder (SUD) Information

In order to be valid, a written consent to disclose SUD information under Part 2, must be in writing and include all of the following items:[7]

1) the name or general designation of the program(s) or person(s) making the disclosure;

2) the name or title of the individual(s) or the name of the organization(s) receiving the disclosed information;

3) the patient's name;

4) the purpose(s) of the disclosure(s);

5) how much and what kind of information to be disclosed;

6) the signature of the patient (and/or other authorized person);

7) the date on which the consent is signed;

8) a statement that the consent is subject to revocation at any time except to the extent that the program or person which is to make the disclosure has already acted in reliance on it; and

9) the date, event or condition upon which the consent will expire if not revoked before.

As stated above, Part 2 currently requires that a valid consent form list the name or title of the individual or the name of the organization "to whom" disclosure is to be made. It is recognized that the intent of the specificity required in the "to whom" section is to allow the patient to be able to identify, at the point of consent, exactly which individual or entity he or she is authorizing to receive his or her SUD information. Clearly, to the greatest extent possible, patients should be fully informed as to who will be the recipients of their SUD information.

Contemporary integrated care models rely on a variety of subsidiary entities performing various intermediary activities for other health care providers. All the entities involved in the coordinated care system require the ability to transfer the necessary amount of the patient's SUD information among themselves via an interoperable health information exchange system.

One of the greatest challenges to implementing a system wide transformation focused on collaboration and integration of health care providers is that it is extremely difficult, if not impossible, to prospectively specifically identify all of the necessary participants in the integrated care system who must have access to the patient's SUD information at the time the individual is consenting to the disclosure of his or her protected SUD information. The Part 2 requirements around specifying the recipients of confidential information have sometimes hampered the sharing of crucial SUD information at the early stages of projects when individuals in crisis are often most vulnerable. The ability to obtain the individual's consent to share his or her SUD information with an initially undesignated member of a class of recipients would significantly assist in ensuring that all necessary recipients could obtain the individual's SUD information and thereby fulfill their particular responsibilities as providers in the health care delivery system providing services to that member.

Performing Provider System (PPS) and the Delivery System Reform Incentive Program (DSRIP)

The New York State "Delivery System Reform Incentive Payment Program" (DSRIP) is a five-year plan designed to restructure New York's health care delivery system by making major investments in the Medicaid program and is expected to reduce avoidable hospitalizations by 25%.[8] It is intended to transform the health care system into a comprehensive program in which doctors, clinics, hospitals, medical and community-based providers work together to build an enhanced health care delivery system that benefits individual members as well as the communities in which they live. The goal is to form collaborative groups of health care providers known as a "Performing Provider System" (PPS), which will establish partnerships that collaborate in DSRIP project plans designed to ultimately lead to a fundamentally different health care system with a greater emphasis on community-based ambulatory care. PPS providers engage in specific DSRIP projects from a predetermined State list that have been identified as addressing the particular needs of the communities they serve.

All individuals enrolled in Medicaid automatically become part of the DSRIP program and receive the benefits provided by PPS providers. Medicaid beneficiaries are assigned to a PPS based on their "loyalty" pattern, i.e., a review of the utilization of their prior history of services. Geography and health plan primary care physician selection are also factors used in assignment. Designated PPS leads are responsible for ensuring that their PPS meets all the DSRIP protocols. PPS leads and their providers monitor the quality of care and the health of the community and their members by accessing, collecting and submitting health information to DOH, identifying populations at risk, implementing new care sites and services, ensuring continuous improvement in services and sharing in incentive payments based on achieving successful outcomes.

DOH provides the PPS leads with lists of members attributed to their PPS. To enable PPSs to meet the needs of these attributed members DOH shares Medicaid claims data with the PPS leads. This data originated from the member's PCP, and other service providers within the PPS network and is stored by DOH in a database that can be accessed by PPS leads and authorized providers. This database is known as the Medicaid Analytics Performance Portal (MAPP).[9]

Flow of Information

DOH chose to use an opt-out process as the mechanism for obtaining DSRIP consent. To "opt out" means electing NOT to permit the sharing of PHI and other Medicaid data held by DOH to the PPS lead and its providers. Pursuant to this process, unless the Medicaid member formally opts out of DSRIP data sharing, it is considered participating in DSRIP data sharing. Members can opt in or out of data sharing at any time.

The PHI which is shared includes Medicaid claims information for the last several claims on record. However, because Part 2 requires an individual's affirmative consent, all SUD information had to be expunged from the Medicaid data prior to it being shared. In order to ensure that all SUD treatment information was removed, OASAS and DOH data experts developed sophisticated expunge logic, completed user acceptance testing and validated the functionality of the logic. While excluding SUD information protects a member's confidentiality, it unfortunately fails to provide the PPS and its providers a complete representation of a member's health care history and potential needs.

To the extent that the PPS lead and its providers receive only non-SUD PHI, they must obtain the member's consent to access any SUD information. Presently, in order to obtain the member's consent the PPS providers must reach out to each other and request that their providers solicit the necessary consent from any members who may be receiving SUD treatment. While this consenting process is a workable solution, it is not ideal. This sometimes results in the PPS providers obtaining multiple consents to stitch together the connections among PPS providers in order to permit the necessary exchange of SUD information within the PPS network.

SAMHSA's Proposal to Permit a General Designation of Recipients

SAMHSA recently published a notice of a proposed rulemaking which incorporates a modification of the Part 2 consent requirements with the goal of facilitating broader participation by SUD treatment patients into an integrated care system.[10]

SAMHSA's proposal results in a subtle but significant change, as it allows the patient to consent to an individual or entity, which may not be specifically identified at the time the individual provides consent to access their SUD information. SAMHSA proposes to accomplish this by permitting a "general designation" for individuals or entities who have a treating provider relationship with the individual whose records are being disclosed. Allowing a general designation represents a realistic approach in today's environment of health homes and other care coordination systems. The ability to generally designate a class of recipients addresses the increasingly common scenario where the individual knows that certain services may be offered, but does not immediately know which particular provider participant within a health home, or coordinated care system will actually provide those services.

Allowing the general designation of the recipient does not diminish the patient's confidentiality as this change remains tempered by Part 2's other consent requirements which require the consent to specifically identify the SUD information being disclosed; the purpose for which it is being disclosed relative to each particular recipient; and Part 2's prohibition on redisclosure. Maintaining these existing requirements should assure that disclosed SUD information is accessed and used only as the patient intended.

PPSs have a legitimate need to access the individual's SUD identifying information so that these entities can assist in facilitating the overall provision of integrated care to the individual and accomplish the specific health and recovery goals outlined in PPS projects. PPSs are generally responsible for validating whether claims submitted by providers have in fact been delivered; monitoring the individual's utilization of health care services; and allotting proportional cost savings to participating providers. In order for PPSs to accomplish these functions, they require the individual's authorization to access and disclose patient-identifying SUD information.

Providing the flexibility of a generalized description permits the individual to consent to the disclosure of varying amounts of patient-identifying SUD information to all known individuals and entities, for specific purposes, while recognizing that the individual is also consenting to the disclosure of their SUD information to a presently unidentified entity, such as the PPS, who will provide a particular service for treating provider participants within the integrated health care delivery system.

For example, where an individual is enrolling in a Medicaid managed care plan, administered by an identified managed care provider, which includes amongst its provider participants the patient's SUD treatment program, as well as the patient's Primary Care Provider

(PCP), all of the known entities can be specifically identified on the consent, as can the amount and kind of SUD information, if any, each identified recipient requires to fulfill the particular purpose for which the disclosure is being made. This is consistent with the existing regulations and practice.

Although the specific entity, within a generally designated class of entities, which will provide a known service, such as a PPS, may not be identifiable at the time the consent is signed, what is known is the purpose, or what particular service is to be provided, such as by a PPS, as well as the amount and kind of the individual's SUD information that the PPS requires to perform the designated service. Once the identity of the PPS provider is determined, the patient can be informed of the identity of the appointed provider which is performing the identified service.

Since the initially generally designated PPS provider will be employed to provide a facilitating service among the identified health care system providers, and will actually be identified once selected, the individual's consent to permit disclosure to an initially generally designated class of participants (such as PPSs) does not necessarily result in any diminution of the confidentiality protections afforded SUD patients.

Consequently, OASAS supports the proposed flexibility of allowing identifying a recipient by a general designation as opposed to specifically naming the organization. A valid consent can reflect the patient's authorization to disclose his or her SUD information to an individual or entity which is initially only a general designated. This is acceptable because the specific purpose or identified service is to be provided by the generally designated provider within the integrated health care delivery system is also specifically identified in the consent.

Consistent with existing requirements, the disclosure of the SUD information to all designated recipients must be limited to only the actual entity which requires access to, and use of, the individual's SUD information, for the purpose of performing the designated function for the benefit of the patient as specified in the consent.

Disclosure of Medicaid Information

Although the Medicaid implementing regulations[11] permit the disclosure of SUD patient identifying information concerning Medicaid recipients, the disclosure of such SUD information is conditioned upon compliance with the Federal Confidentiality provisions.[12]

As stated above, one of the fundamental expectations regarding the protection of confidential information is that where an individual's SUD information is received for a particular purpose, it cannot be later redisclosed for some other purpose unless the individual provides a subsequent consent, or there exists some other exception to Part 2.[13]

Consequently, although the NYS Department of Health (DOH) possesses enormous amounts of Medicaid data, DOH must obtain the consent of any individual whose SUD information is protected by 42 CFR Part 2, so that his or her information may be disclosed to facilitate the purposes of DSRIP.

New York's Electronic Health Information Exchange

Part 2 permits patient identifying SUD information to be disclosed to, and through, Health Information Exchange (HIE) organizations; however, such exchange is still subject to the individual's consent to such disclosures. Obtaining the patient's consent is sometimes perceived as a barrier to the electronic exchange of health information. However, it is possible to electronically exchange information while also meeting the requirements of Part 2.

The exchange of the SUD information among and between the PCP, PPS and other providers is facilitated by the utilization of HIE organizations run by a local Qualified Entity (QE). New York State currently has eight QEs which are secure local hubs where a region's electronic health information is stored and shared. The New York eHealth Collaborative (NYeC) is New York State's designated entity to coordinate the QEs into a Statewide Health Information Network for New York (SHIN-NY). The SHIN-NY is a "network of networks" that links the eight QEs throughout the state.[14]

Each QE operates a network that collects electronic health records from participating providers. With patient consent, the QE allows those records to be accessed securely by other healthcare providers in their local community. Before SUD information can be exchanged among, and accessed by, providers the patient must authorized such exchange and access. The patient provides this authorization through the execution of a multi-party consent form which complies with the requirements of Part 2.

Incorporating Part 2 Consent Elements into the Medicaid Enrollment Application (MEA)

In an effort to facilitate the electronic exchange of SUD information in an era of dramatically evolving health care system, OASAS has been working the DOH to incorporate the required elements of a valid Part 2 consent into the NYS Medicaid Enrollment Application (MEA). SAMHSA's willingness to permit increased flex-

ibility in the regulation substantially assists in permitting the MEA to become a generalized, multi-party consent at the time individuals are enrolled in Medicaid.

Upon the individual's enrollment and election of a Medicaid managed plan, all known plan participants are identified to the individual/member. The member then provides consent to allow the applicable entities, both specifically and initially generally designated, to access and share the Applicant's SUD information. Essentially, once the member signs the MEA and chooses the Plan, they authorize DOH to share his or her Medicaid medical information, including his or her SUD information, if any, with all of the providers delivering services directly to the member.

The consent portion of the Application explicitly identifies the Applicant's past treatment providers, and Medicaid Analytics Performance Portal (MAPP) as potential sources of protected information. Additionally, the member acknowledges and consents to his or her information being shared via a QE and through the SHIN-NY exchange system and that his or her PHI will be accessed and shared by those entities who are, or will be, providing treatment, processing payments or monitoring quality of the care provided to the member.

The use of the MEA as an initial consent form does not necessarily eliminate the need for subsequent consent forms. As the member receives services from health care providers, or other necessary service providers identified by the Plan administrators, subsequent consent forms will be required to permit disclosure of SUD information to any entity not initially identified in the MEA. However, the use of the MEA as an initial consent will greatly facilitate the provision of health care services to those individuals most in need of medical treatment.

Conclusion

Protecting the confidentiality of a SUD patient's identity remains as essential today as it was when the federal law was first enacted. Information-sharing is key to the success of any health care initiative. Balancing a SUD patient's right to confidentiality with the opportunities afforded him or her in the dynamic and evolving world of health care requires parties involved in any new initiative to take a thoughtful and deliberate look at how all information will flow among the parties well before the program is fully designed. To ensure the successful integration and management of SUD patients into the modern health care system, regulators, insurers and health care providers must work together to identify any data sharing challenges early on so that solutions can be worked into the design. Often it only requires a conversation and those are occurring in New York.

Endnotes

1. See 42 CFR § 2.3(a).
2. See 42 CFR § 2.12(a)(1).
3. See 42 CFR § 2.11.
4. See 45 CFR Parts 160 and 164.
5. See 45 CFR Parts 164.506(a), 164.506(c).
6. See 42 CFR §§ 2.31 et seq.
7. See 42 CFR § 2.31.
8. See http://www.health.ny.gov/health_care/medicaid/redesign/dsrip/.
9. See https://www.health.ny.gov/health_care/medicaid/redesign/dsrip/data_security/dsi_faq_7-15-15.htm.
10. See https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-01841.pdf.
11. See 42 CFR § 431.300.
12. See 42 CFR § 2.1(a).
13. See 42 CFR §2.12(d)(2)(i).
14. See http://www.nyehealth.org/shin-ny/what-is-the-shin-ny/.

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DSRIP: NY Medicaid Program's Transition to Value Based Payment Arrangements

By Laurie Cohen, Michael Taubin and JoAnna Nicholson

I. Background—Medicaid Reform

The Medicaid Redesign Team (the "MRT"), established by executive order, was charged with the task of finding ways to save money within the Medicaid program for the state budget for the 2011-12 Fiscal Year.[1] In Phase I, the MRT made a number of recommendations to reduce immediate spending, including the implementation of a "global cap" on state Medicaid expenditures enforceable by the Commissioner of Health.[2] Recognizing that survival under the global cap would require significant reform and innovation, the MRT submitted an amendment to New York's Partnership Plan demonstration 1115 waiver, in which the MRT sought permission to reinvest Medicaid savings realized from its reform efforts back into Medicaid to support additional reforms and to implement program changes called for in the Affordable Care Act.

The Centers for Medicare and Medicaid Services ("CMS") approved the proposed amendment in April 2014, allowing the state to reinvest over a five year period $8 billion of federal savings generated by MRT reforms through the Delivery System Reform Incentive Payment (DSRIP) program. Under DSRIP, the state's safety net providers, organized into twenty-five "Performing Provider Systems" (PPSs), are required to collaborate to implement an array of projects focusing on system transformation, clinical improvement and population health improvement, with the goal of reducing avoidable hospital use by 25% over the five years of the program.[3] The PPSs receive incentive payments directly from the New York State Department of Health ("DOH") based upon the achievement of certain milestones reached for each project. PPSs are also eligible to receive additional payments if they exceed the target milestones.[4]

The metrics used to determine milestone payments are divided into four domains: overall project progress metrics (Domain 1), system transformation metrics (Domain 2), clinical improvement metrics (Domain 3), and population-wide project implementation metrics (Domain 4). The clinical improvement milestones are further divided into process milestones (those that denote system changes, like training or the adoption of EHRs) and outcome milestones (changes that evidence a change in the healthcare system, like improved control of diabetes or reduction in avoidable hospital use).[5]

In its second year, the DSRIP program continues in its efforts to transform the state Medicaid system. The PPSs are implementing their projects and submitting their quarterly performance reports. Most are substantially achieving their initial project milestones and earning most of their DSRIP award dollars for such performance. These project efforts will continue throughout the five year program.

At the same time, further attention is being paid to another significant goal of the DSRIP program, namely, the shift from a volume-based to a value-based payment system by the end of the five-year program. Having identified payment reform as a critical factor in the long term success of any efforts to reform the state's Medicaid program, managed care organizations ("MCOs") and providers participating in DSRIP will be required to move away from fee-for-service payment models. The expectation is that the payment reform will support the broader health system reforms and continue beyond the end of the DSRIP program, and further influence changes in the state's broader healthcare system. In its first update to the New York State Roadmap for Medicaid Payment Reform ("VBP RoadMap") the state has set forth its plan for all Medicaid managed care organizations (MCOs) to employ value based payments methodologies for at least 80% of managed care payments to health care providers by April, 2020.

II. VBP Road Map—Importance of changing payment methodologies

CMS conditioned DSRIP funding on the state's development of a multi-year "roadmap" outlining the state's plan for how it will amend the payment arrangements and accountability mechanisms for its managed care contracts to reflect the goals of DSRIP.[6] In the summer of 2015, CMS approved the initial VBP Roadmap. The first annual update to the VBP Roadmap was released in March 2016 and is subject to CMS approval. The VBP Roadmap offers guidance to payors and providers with respect to the structure of acceptable value based payment models and the expected timeline for moving away from fee-for-service arrangements. However, there is still uncertainty with respect to the implementation of VBP arrangements, as the metrics for determining value under these arrangements have still not been finalized and will undergo continued review in collaborations between the state and the stakeholders.

The MRT identified early on in its reform efforts that the practice of paying for volume rather than for value

would undermine any attempts to improve health outcomes and efficiencies in the health care delivery system. Simply using existing fee for service payment systems to pay providers perpetuates the misaligned incentives associated with the current system.[7] According to DOH, payment reform is required to prevent the return of "value-destroying care patterns" (i.e., avoidable (re) admissions, ED visits) after the five-year DSRIP program. In addition, payment reform is necessary to ensure that savings realized from DSRIP do not merely accrue to MCOs, due to improved performance on DSRIP outcomes (reduced admissions, reduced ED visits, etc.).[8]

Proposed VBP Models

While the state does not intend to prescribe a single path to VBP for all providers and MCOs, it has recommended four (4) value-based payment models categorized by the types of integrated services offered and target populations, which will allow providers and MCOs to select arrangements that they can sufficiently manage and support. DOH has, however, stated that the most important VBP standard is a need for consistency in VBP definitions. This consistency is a key factor in achieving success and includes clear definitions of "the services to be included and excluded from each model; members eligible for attribution to each model; selection and specifications of quality and outcome measures for each model; and methods to calculate the risk adjusted cost of care in each model and in benchmarks used by the State to reflect changes in the clinical and demographic mix of attributed members."

The models are as follows: (1) the provider can assume responsibility for the total care for the general Medicaid population; (2) the MCO can contract with patient centered medical homes or advanced primary care arrangements and reward those providers based upon savings and quality outcomes; (3) the provider can assume responsibility for outcomes and costs of care associated with specific bundles or episodes of care, such as maternity care or certain specified disease conditions; or (4) the provider can provide total care for certain specified subpopulations that experience severe co-morbidities or disabilities.[9]

As noted above, each of these models will be standardized through defined sets of covered services, member eligibility requirements, quality and outcome metrics, and risk-sharing methodology, which will ensure that consistency in reporting requirements, which should reduce the administrative burden for both MCOs and providers.[10]

The VBP Roadmap sets forth the various ways in which the MCOs and providers can create combinations of these models. In addition, the state will also permit MCOs and providers to agree to other "off menu" arrangements as long as they promote payment reform and conform to the criteria set forth in the VBP Roadmap, including a focus on both outcomes and the cost of care delivered. These "off menu" arrangements will be subject to periodic audits by the State.[11] Examples of "off menu" arrangements include bundles for conditions that are not specified in the VBP Roadmap, or total care for subpopulations not included in the VBP Roadmap.

Levels of Contracting

The VBP Roadmap sets forth for each of the proposed models four levels of value-based-payment contracting arrangements that reflect a continuum of upside and downside risk-sharing agreements that will assist MCOs and providers in moving away from fee-for-service compensation. A Level 0 arrangement is essentially fee-for-service with a possible performance-based payment, and is not considered value-based payment. Level 1 arrangements, consisting of upside-only shared savings between the MCO and provider, and Level 2 arrangements, which involve both upside and downside risk, which are based upon a retrospective reconciliation of fee-for-service payments. Under Level 3 arrangements, there is no retrospective reconciliation because the fee-for-service payment system is replaced by a per member per month and/or prospective bundled payment.[12] Providers will be incentivized to pursue higher levels of VBP through increases in their target budgets. Beginning in 2018, MCOs will be penalized for falling behind the goals of VBP Roadmap, and it is expected that these penalties will be passed down by the MCOs to inefficient providers that resist entering into VBP arrangements.[13]

In order to protect providers from assuming more risk than they can sustain, contracts will be subject to a single or multi-agency review process depending on the level of financial risk being assumed by the provider. In addition, DOH has indicated that financially challenged providers cannot enter into Level 2 of higher VBP arrangements.

Options	Level 0 VBP	Level 1 VBP	Level 2 VBP	Level 3 VBP (only feasible after experience with Level 2; requires mature VBP contractor)
Total Care for General Population	FFS with bonus and/or withhold based on quality scores	FFS with upside-only shared savings when quality scores are sufficient	FFS with risk sharing (upside available when outcome scores are sufficient; downside is reduced or eliminated when quality scores are high)	Global capitation (with quality-based component)
Integrated Primary Care	FFS (plus PMPM subsidy) with bonus and/or withhold based on quality scores	FFS (plus PMPM subsidy) with upside-only shared savings based on total cost of care (savings available when quality scores are sufficient)	FFS (plus PMPM subsidy) with risk sharing based on total cost of care (upside available when outcome scores are sufficient; downside is reduced or eliminated when quality scores are high)	PMPM payment for primary care services (with quality-based component)
Bundles	FFS with bonus and/or withhold based on quality scores	FFS with upside-only shared savings based on bundle of care (savings available when quality scores are sufficient)	FFS with risk sharing based on bundle of care (upside available when outcome scores are sufficient; downside is reduced or eliminated when quality scores are high)	Prospective bundled payment (with quality-based component)
Total Care for Subpopulation	FFS with bonus and/or withhold based on quality scores	FFS with upside-only shared savings based on subpopulation capitation (savings available when quality scores are sufficient)	FFS with risk sharing based on subpopulation capitation (upside available when outcome scores are sufficient; downside is reduced or eliminated when quality scores are high)	PMPM capitated payment for Total Care for Subpopulation (with quality-based component)

Source: New York State Roadmap for Medicaid Payment Reform—2016 Annual Update

Key Components of a VBP Contract

A provider's existing participation agreement with MCO will be the foundation for a VBP contract. In pursuing a VBP contract, there are, however, certain key components of the arrangement upon which the provider and MCO must agree. These include: the performance measurement period for the contract; how to establish the target budget, i.e., a percentage of premium or a set dollar amount; the services to be included as well as applicable carve-outs; the process for calculating performance; how savings and losses will be allocated; reporting requirements; and the quality or performance metrics which must be met as a condition of sharing savings. Depending upon the level of risk to be assumed by the provider, the parties may also need to arrange for certain financial protections such as stop-loss insurance or a line of credit to address possible shared losses.

Additional Regulatory Support for VBP

The state will also seek regulatory and statutory amendments that will support the VBP models, including, but not limited to, amendments to the state Stark and anti-kickback statutes to be consistent with federal laws and regulations. In addition, to drive MCO and provider behavior, DOH is also in the process of updating the Medicaid MCO Model Contract to incorporate VBP initiatives and standards set forth in the VBP Roadmap.[14] DOH has also released a draft of revised New York State Department of Health Provider Contract Guidelines for MCOs and IPAs to "modify the contract submission and review process to reflect Value Based Payments arrangements."[15]

The draft Guidelines create three tiers for contract review by DOH as opposed to the current five tiers. The first tier would be a file and use in which DOH will conduct what it describes as an abbreviated review to ensure certain programmatic requirements are met and would apply to contracts with minimal financial risk. Tier 2 contracts would trigger financial and programmatic review by DOH and are limited to contracts that transfer financial risk for a single specific service or multiple services provided directly by the providers accepting the risk. Tier 3 contracts would be subject to programmatic review by DOH and financial review by the Department of Financial Services and at DOH's discretion may also be subject to financial review by DOH. Tier 3 contracts would involve the transfer of substantial financial risk to providers where the prepaid capitation payments are more than $250,000.

VBP Timeline

While the overall goal is to have 80-90% of total Medicaid MCO/contractor payments (in terms of total dollars) made using non-fee-for-service payment methodologies by April 2020, PPSs and MCOs will be required to take specific action toward VBP in the next two years. PPSs must submit their plan for moving their participating providers toward 90% value based payments by April 1, 2017. If a PPS wants to engage in VBP contracting, the state has clarified that the PPS must become an accountable care organization ("ACO") certified by DOH or must form an independent practice association ("IPA") in order to contract with an MCO. An IPA or ACO formed by a PPS, however, does not necessarily need to include all providers in its network for purposes of VBP contracting. If the PPS does not evolve into an ACO or IPA, it must nonetheless support its network of providers to transition to VBP arrangements. In addition, MCOs are required to demonstrate that at least 10% of their total expenditures are captured in a Level 1 arrangement or higher by April 1, 2018.[16] Based upon a recent survey of health plans, it appears than MCOs are already at or above 25% of VBP. By April 2019, 50% of total MCO payments should be contracted at Level 1 or above and at least 15% at Level 2 of above. By April, 2020, 80-90% of MCO payments (in terms of total dollars) will need to be at Level 1 or above and at least 35% at Level 2 or above.

Quality Measures/Metrics

The selection of quality measures for the VBP models has been addressed by Clinical Advisory Groups ("CAGs"), the members of which reflected both upstate and downstate stakeholders as well as the spectrum of practitioners relevant to the care for the specific conditions and subgroups at issue. The quality measures were developed by the CAGs using the relevant DSRIP Domain 2 and 3 measures, as well as other state, CMS and nationally recognized quality metrics, such as New York's Quality Assurance Reporting Requirements.[17] While the initial set of quality measures have been identified by the CAGs, they will be reviewed and finalized in 2016, with the details to be issued in "Playbooks" that will be updated annually.[18]

VBP Pilot Program

To support the efforts of PPS and their providers who are seeking to gain early experience with VBP arrangements, DOH has also announced a two-year VBP pilot program. The state expects to approve up to 15 pilot projects in late spring 2016, with 2-3 pilots testing one of each of the care models. In the second year of the pilot, the providers must assume some downside risk. Depending on the VBP model selected, there are minimum attributed lives required: at least 10,000 lives for the total care model, 5,000 lives for the subpopulation model and at least 1,000 lives for the primary care and bundled care models. In addition to gaining experience with VBP, selected PPSs and/or providers will also receive analytical and techni-

cal assistance from the DOH and KPMG in structuring the pilot projects which are expected test the various VBP models and provide insight on ways to refine the VBP models and associated quality measures.

VBP Bootcamps

To further assist MCOs and providers with the transition to VBP arrangements, DOH has also scheduled a series of bootcamps to educate stakeholders about VBP.[19] The VBP bootcamps will be held throughout the state and each bootcamp consists of three full-day sessions. The first session is an introduction to VBP and the state's visions as set forth in the VBP Roadmap. The second session is devoted to VBP contracting between MCOs and providers and the third session will focus on "performance measurement and how performance results will impact the adjustment (upward or downward) in target budgets and shared savings/losses."

DOH's materials from the early sessions of the bootcamps include guidance for providers as they assess their preparedness to assume risk through value based payment arrangements. DOH recommends that providers perform a readiness assessment that focuses on a number of key areas including financial sustainability, organizational readiness, information technology capabilities, care delivery and partnerships. The materials set forth the steps that both beginner and experienced contractors should take to move toward value-based payments, and provide key questions that providers should be reviewing in determining whether they are prepared to enter into value based payment arrangements. In addition, the materials include indicators for each of these areas that signal that the provider is in an ideal position to begin assuming risk. For example, with respect to care delivery, a provider may be prepared to enter into value-based payment arrangements if it has experience managing care for groups of members and/or populations with various conditions. Similarly, a provider may be prepared to assume risk from a partnership perspective if it has established appropriate partnerships with other providers and social services organizations to meet community needs.[20]

III. Conclusion

The State's goals as set forth in the VBP Roadmap are ambitious and the timeline is relatively short considering the level of change that is expected. All stakeholders, however, have a vested interest in moving forward to achieve the goals or risk that CMS could find that the State has not delivered on the reforms promised and therefore, might be expected to refund in whole or part the DSRIP dollars.

Endnotes

1. Executive Order No. 5: Establishing the Medicaid Redesign Team, Jan. 5, 2011, http://www.governor.ny.gov/news/no-5-establishing-medicaid-redesign-team (last visited Aug. 29, 2016).
2. New York State Dep't of Health: A Plan to Transform the Empire State's Medicaid Program (hereinafter "MRT Redesign Plan"), at 4, https://www.health.ny.gov/health_care/medicaid/redesign/docs/mrtfinalreport.pdf (last visited Aug. 29, 2016).
3. New York State Dep't Of Health Medicaid Redesign Team, A Path toward Value Based Payment: Annual Update June 2016: Year 2, New York State Roadmap for Medicaid Payment Reform (March 2016) (hereinafter, "VBP Roadmap"), at .3, available at https://www.health.ny.gov/health_care/medicaid/redesign/dsrip/docs/1st_annual_update_nystate_roadmap.pdf (last visited Aug. 29, 2016).
4. Centers for Medicare and Medicaid Services, New York State Partnership Plan Medicaid Section 1115 Demonstration Waiver Number 11-W-00114/2, Special Terms and Conditions (herein after "DSRIP Special Terms"), Attachment I, at 37, available at https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ny/ny-partnership-plan-ca.pdf (last visited Aug. 29, 2016).
5. New York State Dep't of Health, DSRIP Frequently Asked Questions (FAQs), at 29 (DSRIP Reporting and Payments, #17), available at https://www.health.ny.gov/health_care/medicaid/redesign/docs/dsrip_faq.pdf (last visited Aug. 29, 2016).
6. DSRIP Special Terms, at 36, 67-68 (Special Term and Condition 39).
7. MRT Redesign Plan, at 33.
8. VBP Roadmap,at 7.
9. VBP Roadmap, at 11-15.
10. VBP Roadmap pgs. at 11.
11. VBP Roadmap, at 11-12, 65 (Appendix II).
12. VBP Roadmap, at 21.
13. VBP Roadmap, at 29, 45.
14. VBP Roadmap, at 47-48.
15. New York State Dep't of Health Provider Contract Guidelines for MCOs and IPAs, draft, http://www.health.ny.gov/health_care/managed_care/hmoipa/docs/revised_guidelines_draft.pdf (last visited Aug. 29, 2016).
16. VBP Roadmap, at 60.
17. VBP Roadmap, at 34.
18. VBP Roadmap, at 35.
19. New York State Dep't of Health, DSRIP – VBP Bootcamps, available at https://www.health.ny.gov/health_care/medicaid/redesign/dsrip/vbp_bootcamp/index.htm (last visited Aug. 29, 2016).
20. New York State Dep't of Health, Medicaid Redesign Team, VBP Bootcamp Series, Session 1, Region 1: Capital Region, Mid-Hudson, Southern Tier (June 2016), at 80-92, available at https://www.health.ny.gov/health_care/medicaid/redesign/dsrip/vbp_bootcamp/docs/2016-06-02_session1_slides.pdf (last visited Aug. 29, 2016).

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Excerpts from Recommendations for Amending the Family Health Care Decisions Act to Include Health Care Decisions for Persons with Developmental Disabilities and Patients in or Transferred from Mental Health Facilities

New York Task Force on Life and the Law, Special Advisory Committee, June 21, 2016

I. Introduction

The Task Force on Life and the Law (the Task Force) was established by Executive Order in 1985 to undertake studies of issues arising at the interface of law, medicine, and ethics. In April 1992, the Task Force issued a report examining the ethical issues that arise when making decisions for individuals who lost the capacity to consent to medical treatment, but did not previously appoint a health care agent. The report, *When Others Must Choose: Deciding For Patients Without Capacity,*[1] set forth a proposal for legislation authorizing family members or close friends to decide about treatment for all incapacitated patients who have not signed a health care proxy or left specific oral or written treatment instructions.

The Family Health Care Decisions Act (FHCDA) was enacted in 2010 and included many of the recommendations made by the Task Force.[2] The FHCDA was designed to provide a way for surrogate decision-makers to honor the wishes of patients when those patients could not speak for themselves, or to act in the best interests of those patients when their wishes were unknown.

The FHCDA was influenced by and is similar in key respects to other New York surrogate decision-making laws that had been enacted earlier. The FHCDA's key influences were New York's Do Not Resuscitate (DNR) Law,[3] which authorized surrogate decision-making for resuscitation decisions, and the Health Care Decisions Act for Mentally Retarded Persons (HCDA),[4] which authorized surrogate end-of-life decision-making for incapacitated patients with developmental disabilities.

Prior to the passage of the FHCDA, family members and close friends of patients who were not covered by other limited surrogate decision-making laws did not have clear authority to consent to routine or major medical health care decisions on a patient's behalf. Family and friends also lacked any authority to make decisions other than DNR regarding the withdrawal or withholding of life-sustaining treatment.[5] As a result, family and friends faced barriers in making health care decisions based on their loved one's reasonably known wishes or best interests.

The FHCDA allows an incapacitated patient's family member or close friend to be designated by law as a surrogate for making health care decisions for an incapacitated patient who did not already make health care decisions or appoint a health care agent. In addition to making routine health care decisions, the surrogate is authorized by the FHCDA to direct the withdrawal or withholding of life-sustaining treatment from the incapacitated patient in specified clinical circumstances, based on the latter's wishes or, if wishes are not reasonably known, best interests.[6] The FHCDA only applies to decisions relating to treatment in hospitals, which means general hospitals,[7] nursing homes, or hospices.[8,9] For individuals outside of these health care settings, the Task Force, in a 2012 report, proposed extending the FHCDA to residential settings.[10] This proposal would allow surrogates to make life-sustaining treatment decisions on behalf of incapacitated individuals (including those with mental illness) in residential settings under a similar framework to that already required in medical facilities.

When the FHCDA was enacted, certain populations were excluded from the law because they were covered under existing laws like the Health Care Decisions Act for Mentally Retarded Persons (HCDA). Lawmakers wanted to study whether the FHCDA could appropriately be extended to meet their needs and circumstances. In the FHCDA the legislature explicitly assigned to the Task Force the project of considering whether the FHCDA should be amended "…to incorporate procedures, standards and practices for decisions about the withdrawal or withholding of life-sustaining treatment from patients with mental illness or mental retardation or developmental disabilities, and from patients residing in mental health facilities."[11]

In performing this task, the FHCDA required the Task Force to form a Special Advisory Committee (SAC) with six Task Force members, three members selected by the commissioner of the Office of Mental Health, and three members selected by the commissioner of the Office of Mental Retardation and Developmental Disabilities (now the Office for People With Developmental Disabilities). The Task Force formed this committee, which then sought comments from interested persons in the mental health and developmental disability communities including providers, patients, and advocates. The committee carefully considered all input and used its expertise to create recommendations for amendments. These recommendations were vetted by several rounds of discussion and debate, and the SAC tested the practical implications of their recommendations for patients in several plausible scenarios through a series of "table-top" exercises. SAC members designed situations involving hypothetical patients who differed according to several factors: location,

health condition, mental condition, surrogate, and surrogate's disposition toward the patient. With the assistance of an experienced clinician, the SAC determined how the amended laws would apply to health care decisions for these hypothetical patients. These exercises helped the SAC refine the language of their recommendations.

After reviewing the SAC committee's reasoning and recommended amendments, the Task Force accepted and approved the report and the proposal to amend the FHCDA and HCDA to clarify and streamline the relevant decision-making processes while preserving certain protections in existing law specific to each population.

Endnotes

1. *Available at*: http://annals.org/article.aspx?articleid=706311.
2. Chapter 8 of the Laws of 2010, codified principally in NY Public Health Law Article 29-CC.
3. NY Public Health Law Article 29-B (1987).
4. L. 2002, ch. 500, codified principally in Surrogate's Court Procedure Act §1750-b.
5. See Robert N. Swidler, *New York's Family Health Care Decisions Act: The Legal and Political Background, Key Provisions and Emerging Issues,* NYSBA Journal 17, at 18 (2010).
6. *See* NY PHL §2994-d(5).
7. Hospitals under the FHCDA refers specifically to general hospitals governed under PHL Article 28, excluding a ward, wing, unit or other part of a general hospital operated for the purpose of providing services for persons with mental illness pursuant to an operating certificate issued by the Commissioner of Mental Health.
8. Hospices under the FHCDA refers specifically to those governed under PHL Article 40.
9. The Task Force has recommended extending the FHCDA to agencies, programs, and health care settings that are Medicare and/or Medicaid-certified and State-licensed.
10. *See Recommendations for Extending the Family Health Care Decisions Act to Medicare and/or Medicaid-Certified and State-Licensed Agencies, Programs, and Settings*, NY State Task Force on Life and the Law, most recently updated 11/26/2012. On file with the Task Force.
11. Chapter 8 of the Laws of 2010 § 28.

IV. Analysis

The Special Advisory Committee (SAC) heard from a number of advocates, patients, and providers from communities representing individuals with mental illness and individuals with developmental disabilities. Advocates representing those with mental illness, including representatives from the Mental Health Empowerment Project, explained that many within their community do not want to be treated differently from the general population. Advocates representing those with developmental disabilities, including representatives from NYSARC, explained that there are times when members of their community, who cannot advocate for themselves, need special safeguards and thus require being treated differently. All advocates expressed a desire for adequate patient protections during end-of-life decisions, to ensure that withdrawing and withholding treatment choices are made according to the patient's wishes and best interests. Speakers also provided insight into the nature of treatment and care in both community and hospital settings, describing the structure of care teams and shared decision-making between providers and patients. In light of these facts, many patient advocates and providers acknowledge the value of existing protections, but believe that amendments could facilitate care that better aligns with patients' wishes and interests.

The SAC examined whether historical and present biases against, and vulnerabilities of, those with developmental disabilities and mental illness justify requiring additional legal checks (beyond those for people who are incapacitated for other reasons) to ensure their lives are not undervalued for end-of-life decisions. Some advocates have expressed opposition to special decision-making rules on the basis of mental health or developmental disability status, whereas other advocates argue in favor of special treatment for the reasons discussed above. The SAC accepts the general principle that end of life treatment decisions should be uniformly protective for all incapacitated populations, regardless of the nature or cause of each individual's incapacity.

The SAC also holds the position that uniformly protective decisions should not imply that choosing to provide life-sustaining treatment is always a superior option to withholding or withdrawing such treatment. The ethos of Western medicine has evolved in recent decades toward accepting that death is not the worst possible outcome of care. Rather, pain and suffering for no medical benefit is the outcome to be avoided. Commonly held moral assumptions of medicine reject the provision of care that increases pain and prolongs the dying process for many, including for patients with intellectual or developmental disabilities.

Determining the optimal balance of clarity, uniformity, and comprehensiveness of protection guided the SAC's decision whether to eliminate or modify the HCDA. Many people who spoke with the Advisory Committee expressed that the HCDA has served a vital function in the State. Its provisions were crafted with careful attention to the vulnerability of individuals with developmental disabilities at the end of their lives. However, the SAC recognizes that greater legal clarity and efficiency might be achieved by unifying the HCDA and the FHCDA. Confusion that results from the current set of divergent standards likely prevents health care practitioners from facilitating timely decisions. The lack of clarity might also be responsible for incorrect administration of surrogate decisions. Health care providers indicated that, at times, legal complexity and certain aspects of mandatory procedure delay the administration of necessary life-sustaining treatment decisions.

Furthermore, disparate laws create concern about equal treatment. Even if the frameworks are followed correctly, similarly situated incapacitated patients might

be subject to different surrogate life-sustaining treatment decisions for no reason beyond differences in governing laws that have no rationale. Such disparate treatment could lead to disparate outcomes that are not predicated on the unique needs of each patient.

For the foregoing reasons, the Special Advisory Committee recommends that the FHCDA and the HCDA should be consolidated and streamlined in order to: make the decision process more intelligible as well as efficient for health care providers and surrogates; protect the rights of all patients to have decisions made according to their wishes and in their best interests; and ensure equal protections for different populations. Specifically, the current surrogate decision-making laws and regulations for patients with developmental disabilities and patients in mental health facilities should be merged into the FHCDA for treatment decisions made in facilities covered by the FHCDA, while preserving those principles and safeguards that have proven necessary for these populations.

Finally, SCPA §1750-b should be adapted to authorize surrogate decisions in settings not covered by the FHCDA (including decisions in residential settings licensed or operated by OPWDD). It should do this by referring to the standards and procedures in the FHCDA, with some adjustments.

The following summarizes the primary issues considered by the SAC with regard to reconciling the FHCDA and the HCDA, and provides rationale for the SAC's legislative recommendations.[1]

Decision-making standards: Members and advocates voiced concern over how to ensure that surrogate decisions accurately reflect the patient's wishes if known, and the patient's best interests. Some advocates and SAC members were concerned that doctors or surrogates might undervalue the quality of life of patients with mental illness or developmental disabilities and might opt for withdrawal or withholding treatment too quickly. On the other hand, the SAC also voiced concern that doctors or surrogates might opt to continue life-sustaining treatment out of personal interests or legal fears. The SAC recommends mechanisms to prevent surrogates from substituting their own judgment in making withholding and withdrawal decisions, and ensure that these decisions for all patients reflect the patient's wishes if known and if not known, the patient's best interests.

The FHCDA prioritizes the patient's wishes over best interests, and includes consideration of the patient's religious and moral beliefs under the category of wishes. Under the FHCDA, if the patient's wishes are not known, then the surrogate should base the decision on the patient's best interests. In contrast, the HCDA requires that the surrogate's decision be based on the patient's best interests and then on the patient's wishes, if known. Many SAC members agree that patient's wishes, when known, should be prioritized over best interests for all surrogate decisions regarding withdrawing or withholding treatment. This prioritization is designed to respect the patient's autonomy. Under this standard, if a patient's wishes are not known or cannot be ascertained, then his or her best interests should form the basis of the surrogate decision.

However, if the patient did not, or cannot, provide an explanation of his wishes that are explicitly tied to withdrawal or withholding life-sustaining treatment, it is important to consider which, if any, of the patient's wishes are sufficient to serve as the decision basis. A patient might have sufficient capacity to express a wish to remove life-sustaining apparatus because it is causing the patient discomfort or fear, while at the same time he or she is unable to comprehend that the result of removal will be the termination of his own life. The SAC spoke with patient advocates and self-advocates from the disability rights community who strongly recommended that individual patients have control over their own end-of-life decisions to the greatest extent possible. Health care providers and caretakers who have a history of attending to the patient should be involved in identifying the patients' wishes and best interests. They noted that some patients who are declared incapacitated for purposes of medical decision-making and who communicate nonverbally, with assistance from close individuals, might still be capable of communicating information relevant to determining their best interests.[2] To respect dignity and personhood, advocates believe that patients with any degree of communication ability should be given the opportunity to provide input regarding the decision, supported by those who know them best, and this input should be taken seriously by decision makers.

The SAC believes that a patient's wishes should be given precedence if the patient expressed relevant wishes at a time when he or she had capacity. Members recommend using the FHCDA standard with minor clarification to ensure that wishes are drawn from a time when the patient had decision-making capacity. The SAC also recommends that individuals close to the patient assist the surrogate decision-maker in considering the patient's past and present wishes.

The SAC recognizes the possibility that some physicians and surrogates might discount the quality or value of a patient's life on the basis of that patient's mental illness or developmental disability. Disability Rights Professor William Peace explains that "people with significant disabilities are at risk of having presumptions about the quality of their lives influence the way medical providers, including physicians, respond to them."[3] In a moving example, Professor Peace, who has been paralyzed since he was eighteen, discussed his own hospital experience in 2010 for a serious open wound. During this event, a physician indicated to Peace that receiving comfort care with the expectation of death might be preferable to treatment that could leave him permanently bedridden and finan-

cially disadvantaged.[4] Professor Peace had the autonomy to navigate his physician's bias framing of treatment options that implied Peace's condition was too great a burden. Unfortunately, the populations that are the subject of this Report may not have such autonomy.

Accordingly, the SAC recommends that language be added to the FHCDA which explicitly prohibits the presumption that people with mental illness or developmental disabilities are entitled to less care, dignity or respect as patients without such conditions. This language is similar to language which currently exists in the HCDA. The SAC also recommends that surrogates should not base their decisions on financial considerations, except as the patient would have wished them to be considered.

Settings of Care: The HCDA currently covers patients in all medical settings, including care at home. However, the FHCDA only covers decisions in general hospitals (excluding a ward, wing, unit or other part of a general hospital operated for the purpose of providing services for persons with mental illness pursuant to an operating certificate issued by the Commissioner of Mental Health), nursing homes, and hospices. Representatives of OPWDD and NYSARC raised the concern that integrating the HCDA into the FHCDA could undermine valuable rights and protections for patients treated in community settings. They opposed the integration of the HCDA into the FHCDA unless the proposed amendments to the FHCDA would preserve decision-making in home and community-based care. That concern includes the need to preserve the current ability of a surrogate and a physician in the community to complete a Medical Orders for Life-Sustaining Treatment (MOLST) form pursuant to the HCDA. To meet these concerns, the SAC recommends amending the HCDA so that people with developmental disabilities are covered by FHCDA standards in all settings, including those not otherwise covered by the FHCDA, like community settings.

In addition, it has become apparent that there is no need for a separate law for DNR orders in psychiatric hospitals and units, and its existence is a source of complexity and confusion. Bills to repeal this vestige of the original DNR law and apply the FHCDA to DNR orders in those settings have been introduced in the state Legislature.[5]

Advocating for Treatment: The HCDA places an affirmative obligation on surrogates to "advocate for the full and efficacious provision of health care, including life-sustaining treatment," whereas the FHCDA does not. The SAC considered whether this provision helps prevent surrogate decisions from being made without adequate consideration of the patient's wishes and best interests, or helps prevent patient's mental illness or developmental disability from being used as a justification for withholding or withdrawing treatment. The SAC does not recommend incorporating the advocacy provision of the HCDA into the FHCDA. The protocol in the FHCDA, with SAC recommended amendments, is designed to ensure that decisions regarding life-sustaining treatment are tailored to the needs of specific patients, which reflects advocacy for the reasonably known wishes, or else best interests of the patient. In some situations, an obligation to advocate for the "full and efficacious treatment" may be contrary to a patient's wishes or even best interests. Including the provision would also violate the general principle of a single standard for all patients. However, the SAC does recommend preserving a provision, adapted from the HCDA that prohibits surrogates or providers from presuming that a person with a developmental disability is not entitled to the full and equal rights, equal protection, respect, medical care, and dignity afforded to persons without a developmental disability. The SAC believes this provision should be extended to prohibit similar presumptions about persons with mental illness.

Expression of a Decision to Withdraw or Withhold Life-Sustaining Treatment: The FHCDA only requires the surrogate to express a decision to withdraw or withhold life-sustaining treatment "either orally to an attending physician or in writing,"[6] whereas the HCDA requires a written decision to be signed, dated, and witnessed, then presented to the attending physician.[7] Under the HCDA, if the surrogate chooses to express the decision to withdraw or withhold life-sustaining treatment orally, this must be done to two adult persons, at least one of whom is the patient's attending physician.[8] The SAC believes that the less rigorous standard employed by the FHCDA—the surrogate communicating the decision directly to the attending physician—is sufficient for ensuring both efficiency and protection against misunderstanding or miscommunication. The physician will confirm that the surrogate understands the implications of the decision, and will apply his or her own professional expertise to verify that the decision complies with the requirements set forth by the FHCDA.

Capacity Determinations: The FHCDA and the HCDA maintain slightly different technical requirements for determination of incapacity for purposes of a decision to withdraw or withhold life-sustaining treatment. The SAC reviewed these standards in the FHCDA and the HCDA to ensure determinations of incapacity that are both accurate and practical, and to ensure those with capacity retain control over their own end-of-life treatment decisions. The FHCDA contains a presumption of capacity for patients, which the SAC recommends preserving except for persons with guardians appointed pursuant to Mental Hygiene Law Article 81 or Surrogate's Court Procedure Act Article 17-A. Regardless of this presumption, for end-of-life decisions, the FHCDA requires the attending physician to determine incapacity to a reasonable degree of medical certainty, and to assess the cause and extent of incapacity, and the likelihood that the patient will regain decision-making capacity. In the opinion of the SAC, the FHCDA standards are sufficient for determinations of incapacity for these populations. For a decision to withdraw or withhold life-sustaining treatment, however, the

SAC recommends using the HCDA standard of capacity determination.

Credential Requirements for Concurring Health Care Professionals: In connection with decisions to forgo life-sustaining treatment, both laws require a concurring (second) determination of incapacity by another practitioner.[9] When the determination relates to a mental illness or developmental disability, both laws require that either the attending physician or a concurring physician possess special qualifications relating to that condition.[10] The requirements for a physician to concur with an incapacity determination due to developmental disability are more rigorous than for concurrence with a determination due to mental illness. Members of the SAC as well as several practitioners that spoke with the SAC report that general hospitals and residential care facilities, especially in rural areas, have had difficulty finding practitioners that meet the qualifications for concurring with an initial determination of incapacity due to developmental disability, which unnecessarily delays the treatment decision process. To address this, the SAC recommends adding another option by which a physician concurring on an incapacity determination due to developmental disability can meet the necessary requirements in a way that mirrors the requirements for an incapacity determination due to mental illness. This option would allow a physician to concur on an incapacity determination due to developmental disability if the physician is certified by a board of psychiatry or is eligible for certification by such a board.

Clinical Determinations: The FHCDA and the HCDA both require that clinical determinations must be made before a surrogate may authorize the withdrawal or withholding of life-sustaining treatment. As a safeguard, both laws require that the determinations must be made by an attending physician, and then confirmed by another physician. The SAC noted that, given the risk of persons with developmental disabilities being devalued, concerns arise when the concurring physician is subject to hierarchical pressures from the attending physician. Notably the FHCDA requires an "independent concurrence by another physician." The SAC encourages hospitals to take steps to ensure that the concurrence is in fact truly independent.

Patients in or Transferred from OMH Facilities: When the FHCDA was being drafted, OMH asked to exclude from FHCDA coverage individuals in or transferred from its facilities. This request was made in order to have additional time to consider whether FHCDA coverage would best protect OMH facility residents. Without FHCDA coverage, there are no rules governing decision to withdraw or withhold life-sustaining treatment for this population. When patients are transferred to general hospitals from OMH facilities, many providers are uncertain as to the proper legal authority guiding decision to withdraw or withhold life-sustaining treatment; others simply assume the FHCDA applies to such patients as it does to all other patients. The SAC recommends extending the FHCDA to patients in or transferred from OMH facilities.

An OMH rule at 14 NYCRR section 27.9 governs major medical treatment decisions for OMH facility residents, but withdrawal and withholding life-sustaining treatment decisions are not explicitly included under "major medical treatment." Under section 27.9, if a patient in an OMH facility does not have the capacity to consent to major medical treatment, consent must be obtained from a spouse, parent, adult child, or a court. Decision-making priority among categories of surrogates is not specified. The SAC recommends applying the FHCDA surrogate hierarchy in these situations.

Mental Hygiene Legal Service Notification: Mental Hygiene Legal Service (MHLS) provides essential advocacy services for people with mental illness and developmental disabilities across New York State. Currently under the FHCDA, MHLS must be notified if a patient transferred from any mental hygiene facility, including those licensed or operated by OMH or OPWDD, is determined incapacitated for purposes of decision to withdraw or withhold life-sustaining treatment. The FHCDA does not require that MHLS be notified for the decision itself. The HCDA does require that notice be given to MHLS prior to implementing the decision. These notification requirements were created to provide vulnerable populations with legal advocacy to ensure that end-of-life treatment decisions are motivated strictly by the patient's wishes and best interests.

Presentations to the SAC by MHLS representatives from the Appellate Division, Third Department confirmed the agency's capacity to provide a critical service during decisions about whether or not to withdraw or withhold life-sustaining treatment for patients incapacitated due to mental illness or developmental disability. Many health care providers who spoke to the SAC described positive collaborative experiences with specific MHLS departments including the third. It was explained that some facilities without general counsel often rely directly on MHLS for legal support during end-of-life decision-making.

Some health care practitioners described experiences in which MHLS routinely objected (formally or informally) to decisions to withdraw or withhold life-sustaining treatment on the basis of having inadequate information about the patient's condition. MHLS's review to ensure these decisions were patient-protective caused delays, which in some cases increased the suffering of patients for whom withdrawal or withholding of life-sustaining treatment was medically indicated.[11]

The SAC recommends a policy that would preserve MHLS's ability to act as an effective patient advocate while recognizing the primary authority of the surrogate, in consultation with the attending physician, to make decisions based on the patient's wishes and interests.

First, the amendment would encourage the clinical team to include MHLS in the clinical team's end-of-life decision process before the surrogate's decision is officially made. The team meeting would include the attending physician, the surrogate, a representative from MHLS, and other care providers deemed essential by the physician and could take place in person or by phone. By being present for this meeting, MHLS would receive comprehensive information about the patient's status and could thus advocate effectively on the patient's behalf.[12] Accordingly, MHLS's participation at this meeting would serve as official notice to MHLS of the decision as required by the FHCDA, eliminating the need for any redundant paper notification. If MHLS is unable to participate in this meeting, the clinical team must provide notice of its decision to withdraw or withhold treatment to MHLS at least 48 hours prior to implementing the decision. MHLS would also be required to provide practitioners with a practical means to notify them at any time, so decisions are not delayed because they need to be made outside of regular business hours.

MHLS may still object to the decision regardless of whether they participated in the clinical meeting. For decisions to withdraw, such objection by MHLS would continue to cause an automatic stay on the withdrawal, preserving the status quo, as it does under the HCDA. But DNR orders are different: if MHLS's objection to a DNR results in an automatic stay, it would not preserve the status quo – in the event of cardiac arrest, this would cause the patient to be subject to an aggressive treatment that the surrogate maintains is contrary to the patient's wishes. There is a need to balance respect for a surrogate's role as the patient's principal spokesperson with the need for MHLS to protect against an unwarranted DNR. Accordingly, the SAC recommends that in the case of an objection by MHLS to a DNR order, in order for the objection to stay the decision, MHLS must provide specific reasons indicating why the surrogate's decision is not supportable under the FHCDA. If these reasons are medical, they must be substantiated by a physician, physician's assistant, or a nurse practitioner. This would prevent delay of time-sensitive treatment decisions that are necessary to honor a patient's wishes or interests and relieve suffering, while allowing MHLS to intervene when it has a legal basis to do so.

These recommendations will afford MHLS the opportunity to be fully integrated in the decision process by ensuring it receives complete and timely information, and allowing it to ask questions of those most intimately involved in the patient's care.

DNR Orders and Intubation: Tracheal intubation often is a critical component of cardiopulmonary resuscitation. For this reason, the SAC's recommendations for requiring specific reasons for an objection to an order not to resuscitate (DNR) in a hospital will also apply to intubation procedures critical to cardiopulmonary resuscitation.

However, it is important to note that a patient's or surrogate's consent to a DNR order does not imply an order not to intubate for conditions unrelated to cardiac arrest. There are situations in which a patient might want life-saving measures such as intubation in the event of respiratory distress, but does not want life-saving measures in the event of cardiac arrest. Accordingly, a surrogate's consent to a DNR order in a hospital typically carries with it a decision not to intubate *for purposes of cardiopulmonary resuscitation*, but may still allow pre-arrest intubation.

Measures to improve ventilation and cardiac function in the absence of a cardiac or pulmonary arrest are explicitly excluded from the FHCDA definition of cardiopulmonary resuscitation.[13] The law does not clarify the relationship between DNR orders and intubation. An amendment to this effect is beyond the scope of the SAC and Task Force's assignment at this time.

Life Expectancy and Other Patient-Condition Requirements: Under both the FHCDA and the HCDA, there are different clinical criteria, outlined on page 16, which must be satisfied before a decision to withdraw or withhold life-sustaining treatment can be implemented. Both laws require that life-sustaining treatment would be an extraordinary burden to the patient. Then, both laws have additional requirements that can be met by choosing from among several options. One option under each law is based on the amount of time the patient is expected to live. Under the FHCDA time option, the patient's condition must be expected to cause death within 6 months, and under the HCDA time option, the patient's condition must be expected to cause death within one year.

The SAC does not believe that maintaining disparate time-frame standards is justified, and recommends only using the one-year expectation. The SAC learned that medical staff members are often reluctant to offer a narrow-window prognosis regarding a patient's time remaining before death largely because this is difficult to predict with accuracy. Evidence suggests that physicians' predictions that a patient will die within a year are more accurate than predictions regarding the number of weeks or months a patient has left to live.[14] The SAC believes that physicians can determine with reasonable accuracy that a patient will die within a year, and using this time frame as one of the options for patient-condition requirements will allow physicians to focus their analysis on whether life-sustaining treatment would provide medical benefit and/or relieve suffering. The time frame requirement does not justify a withholding or withdrawing decision by itself. It must always be accompanied by a determination that treatment would be an extraordinary burden. In conjunction with this latter "quality of life" determination, the SAC believes that a within-one-year "quantity of life" determination creates an ethical basis for a withholding or withdrawing decision.

The SAC also recommends adopting language from the HCDA to prevent consideration of the patient's

developmental disability or mental illness from being used to satisfy the "incurable" or "irreversible" condition requirement. Under the HCDA, a decision to withdraw or withhold life-sustaining treatment may also be considered if life-sustaining treatment would pose an extraordinary burden and the patient has a condition *other than a developmental disability* that requires life-sustaining treatment, is irreversible, and will continue indefinitely. Because the patient's preceding mental status should never form the basis for a life-sustaining treatment decision, this language should be incorporated into the FHCDA to provide a requirement that the patient has an irreversible or incurable condition *other than mental illness or a developmental disability.*

The above two suggested amendments reconcile arbitrary disparities between the FHCDA and the HCDA, and apply a uniformly protective standard to all populations. The SAC believes that amending any other criteria that a patient's condition must meet prior to implementing a decision to withdraw or withhold life-sustaining treatment is beyond the scope of its assignment. It is possible that the evolution of palliative and hospice care since the passage of the FHCDA warrants a future re-examination of these criteria—such as defining "extraordinary burden" or "incurable" or "irreversible."

Preserving Psychiatric Treatment and Behavioral Intervention Provisions in NYCRR: Because of the unique nature of psychiatric treatment and behavioral interventions, the SAC recommends that the current exception under the FHCDA continue in facilities licensed or operated by the Office of Mental Health and facilities or programs licensed, operated or funded by the Office for People With Developmental Disabilities. For patients without legal guardians in psychiatric units, there are regulations promulgated by the Office of Mental Health that govern determinations of capacity for medical decision-making, obtaining consent to treatment from the patient or a surrogate, and processes for objection to treatment.[15] For patients without legal guardians in OPWDD facilities or programs, there are regulations that govern the use of behavioral interventions, including the use of medication, and the process for obtaining consent to such interventions.[16]

These regulations take into consideration circumstances in which the administration of psychiatric treatment, including psychotropic medication, is necessary to reduce danger in emergencies, objections from any party, or lack of consent, notwithstanding.[17] While the FHCDA should be extended to apply to facilities licensed or operated by the Office of Mental Health (OMH) for purposes of general medical treatment and decisions to withdraw or withhold life-sustaining treatment, detailed regulations promulgated by OMH and OPWDD regarding psychiatric treatment or the use of behavioral interventions should remain intact. To this end, the SAC recommends that the FHCDA's definition of "health care" be modified to exclude psychiatric treatment in a facility licensed or operated by OMH or the use of behavioral interventions in a facility or program licensed, operated or funded by OPWDD.

Ethics Review Committee and Special Proceedings: The HCDA explicitly grants surrogates, attending physicians, MHLS, mental hygiene facility CEOs, and OPWDD the right to take disputes (related to decisions to withdraw or withhold life sustaining treatment) to dispute mediation, or to bypass dispute mediation in favor of commencing a proceeding in a court of competent jurisdiction. Under the FHCDA, objections made by the attending physician, a health care professional called upon to concur with a capacity determination or a health care decision, a parent of a minor, or anyone on the surrogate list must be referred to an ethics review committee (ERC) for advisory nonbinding guidance. However, the FHCDA does not preclude persons connected with the case from seeking relief in courts of competent jurisdiction at any time.

Although both laws allow either alternative dispute resolution or resolution by a court of competent jurisdiction, the language of the FHCDA does not emphasize the latter option. The SAC discussed a range of experiences with ethics review committees providing guidance on end-of-life decision disputes. To ensure that objecting parties understand their rights for dispute resolution, the SAC recommends incorporating language into the FHCDA that explicitly grants parties the option of bringing their objections before a court of competent jurisdiction, in addition to the present language that requires referral to an ethics review committee for guidance.

The SAC discussed the need to preserve HCDA dispute resolution guidance for persons with developmental disabilities in all settings, including those beyond health care institutions and residential facilities. It is unclear which mechanism is best suited to resolve disputes over decisions to withdraw or withhold life-sustaining treatment for persons with developmental disabilities in settings like private homes. The nearest hospital ethics review committee might lack expertise in decision-making for those with developmental disabilities. Accordingly, the SAC recommends that the Commissioner of OPWDD have the authority to promulgate regulations for resolving such disputes, which could include convening a panel of individuals with appropriate expertise. In addition, the SAC recommends that a decision by a SDMC should not be subject to ERC review. The SAC also recommends a provision explaining that those involved in the dispute can always bring the case before a court of competent jurisdiction for judicial relief before, during, after, or instead of ethics committee review.

Surrogate Priority: The surrogate priority lists under the FHCDA and the HCDA do not run perfectly parallel. Under the HCDA, parents are given priority above adult children, whereas under the FHCDA, adult children are prioritized above parents. Members of the SAC agreed that if the patient has adult children, they should be given

priority over the patient's parents regardless of the nature of the patient's incapacity. As such, the SAC recommends the use of the FHCDA hierarchy for all populations.

Active Involvement: The HCDA currently requires that a surrogate chosen for decision-making be "actively involved" in the patient's life, whereas the FHCDA makes no such requirement. To resolve this disparity, SAC members considered the following facts. One advocate explained that forty percent or fewer individuals with developmental disabilities in residential care have anyone actively involved enough in their lives who can be called upon to act as surrogate decision makers. It also was explained that individuals with mental illness tend to be even more estranged from family members than those with developmental disabilities. However, the experience of health care providers indicates that individuals who are not actively involved in the patient's life do not come forward to serve as surrogates. If someone on the surrogate list objects to the assignment of a different surrogate, the FHCDA requires the physician to refer the matter to an ethics review committee for resolution.[18]

After discussing the application of an "actively involved" standard for all surrogate decision makers, the SAC decided this requirement would unnecessarily hinder the surrogate appointment process. Advocates explained that those who are available to act as surrogates generally are "actively involved." Including this term in the law would create complications by introducing an ambiguous standard for involvement. It also was explained that health care providers who are concerned about a potential surrogate's lack of prior involvement do not require a legal standard in order to intervene appropriately.

However, one SAC member suggested that, in the case of a person with a developmental disability who is transferred from an OPWDD-licensed facility, the facility director can offer valuable guidance on which person within the priority class has been most actively involved or would serve as a better decision-maker. The SAC believes the attending physician should solicit this information before identifying the surrogate in life-sustaining treatment cases.

Unbefriended Patients and Surrogate Decision-Making Committees (SDMCs): Patients incapacitated due to mental illness or developmental disability who lack an authorized surrogate available and willing to make a decision are assigned different decision-makers under the FHCDA and the HCDA. The FHCDA allows a court of competent jurisdiction to make the decision to withdraw or withhold life-sustaining treatment if the patient is certified to lack capacity, and the patient's condition meets the necessary standards. The FHCDA also allows the attending physician and a concurring physician to make the decision if life-sustaining treatment will offer the patient no medical benefit and the patient will die imminently even if the treatment is provided, and the provision of such treatment would violate acceptable medical standards. The HCDA sends such life-sustaining treatment decisions to Surrogate Decision-Making Committees (SDMCs). The SAC acknowledges that all unbefriended patients are particularly vulnerable to unethical or inappropriate surrogate decisions and deserve equally strong advocacy. The SAC examined whether courts and physicians (under FHCDA) or SDMCs (under the HCDA) provide strong enough representation for both or either population.

The SAC agreed that allowing the attending physician and a concurring physician to make decisions to withdraw or withhold life-sustaining treatment for unbefriended patients incapacitated due to mental illness based on the same "no medical benefit/will die imminently" standard that applies to other patients provides sufficient protections for this vulnerable population. Because these patients are unbefriended, their strongest personal connections are with their health care providers. These providers also have the keenest understanding of their patients' medical conditions. Before implementing a decisions to withdraw or withhold life-sustaining treatment, the attending physician and concurring provider are required to verify that the patient meets the condition requirements set forth by the FHCDA. The attending physician and concurring provider also must make the decision in accordance with the patient's wishes and best interests, as would any other surrogate. If one of these providers bases her decision on any other criteria, then the other will act as a safeguard and could initiate a dispute that will go to an ethics review committee or a court.

For unbefriended patients incapacitated due to developmental disability, it was discussed whether SDMCs convene quickly enough, have adequate decision-making expertise, and are comfortable issuing withholding decisions when necessary. Several SAC members reported positive professional experiences with SDMCs in these situations. The SAC discussed recommending that if a patient is transferred from a residential facility, the SDMC proceeding should include representation from that facility. Some members believed that a judicial process is too time consuming and abstracted from the patient's personal situation to ensure decisions that adequately reflect the patient's wishes and best interests. Accordingly, the SAC recommends incorporating SDMCs into the FHCDA hierarchy list so that they will continue to serve their decision-making function for unbefriended patients incapacitated due to developmental disability.

The SAC also considered a recommendation to extend SDMC decision-making to unbefriended patients with mental illness. However, the SAC decided that requiring SDMCs to serve as surrogate decision-makers for unbefriended individuals with mental illness was beyond the scope of its task. The Justice Center for the Protection of People with Special Needs oversees the operation of SDMCs and as such understands the extent of SDMC resources and capacity, whereas the SAC does not. The SAC

recommends that the Justice Center examine whether this role extension would be advisable.

VI. Conclusion

For years, medicine and the law have poorly served patients without capacity, especially those with mental illness and developmental disabilities, in the end-of-life treatment context. Thorough legal guidance developed in recent years represents a historic shift toward protecting both the wishes and interests of incapable patient populations in their most dire moments. With meticulous effort, discrete groups of policy makers designed the existing laws and regulations discussed in this report that govern end-of-life treatment decisions for patients without medical decision-making capacity and with no legal guardian. The nuanced language of each was crafted to ensure processes that would lead to decisions that most closely align with each patient's wishes and interests. Multiple frameworks for patients who are incapacitated for different reasons and located in different settings came into existence because concerned groups acted on behalf of specific populations.

Now that the FHCDA and HCDA have co-existed for a few years, some facts have led to administrative complication. Patients travel between settings and do not always fit neatly into one framework; the laws have minor arbitrary differences that are difficult to remember; and certain requirement details cause delays during time-sensitive decisions without adding measurable protection. These circumstances have led to sub-optimal treatment for the intended patients.

For almost two years, the SAC of the Task Force on Life and the Law has worked to develop recommendations that alleviate these concerns while preserving the components of the FHCDA and the HCDA that are tailored to the unique needs of specific populations. To shape its recommendations, the SAC studied and debated the fine details of each law, and heard from experts and advocates about the laws in practice. The SAC concluded that for most disparities between the laws that are not necessary to serve differences between populations, the FHCDA will serve all patients without medical decision-making capacity in all settings equally well, with only a few minor modifications. The SAC's recommendations also balance each setting's available resources and practitioner expertise with maintaining standards for arriving at the best decision for each patient. Of equal importance to the SAC was honoring the specific intentions of the crafters of the HCDA. Accordingly, the new recommendations preserve elements of the latter that were hard-fought and won to rectify years of discrimination against people with developmental disabilities.

The SAC's greatest challenge, and hopefully accomplishment, was consolidating the primary substance of these two laws into one while maintaining the crucial tailored differences. Reducing the quantity and complexity of the laws to which practitioners must refer will streamline end-of-life treatment decisions. The recommendations should clarify what process applies in each setting and for each patient. Processes for determining capacity, determining the appropriate surrogate, and guiding, reviewing, and objecting to end-of-life treatment decisions remain entirely focused on enacting each patient's wishes and protecting each patient's interests. It is the SAC's hope that this clarity for providers and respect for vulnerable patients represents the next phase of moral progress in healthcare guidance, building on the essential work of the FHCDA and the HCDA.

Endnotes

1. Some members discussed how educational opportunities, including CME or CLE courses for physicians, family members, and attorneys on the topic of withdrawal and withholding treatment decisions for the incapacitated could be helpful. However, creating these opportunities was determined to be beyond the scope of the present assignment.
2. Close individuals were not necessarily those that would have decision-making authority under either the FHCDA or HCDA, but rather anyone that interacts with the person on a regular basis such as health aides, friends, and others they may regularly encounter.
3. William J. Peace, "Comfort Care as Denial of Personhood," *Hastings Center Report* 42, no. 4 (2012): 14-17, at 15.
4. *See id.*
5. S.7152(Hannon)(2014)/A.9548 (Gunther)(2014); A.1023 (Gunther) (2015).
6. *See* NY PHL §2994-d(5)(e).
7. *See* NY SCPA §1750-b(4)(c)(i).
8. *See* NY SCPA §1750-b(4)(c)(ii).
9. *See* NY PHL §2994-c(3) & NY SCPA §1750-b(4)(a).
10. *See* NY PHL §2994-c(i)-(ii) & NY SCPA §1750-b(4)(a).
11. Descriptions of experiences with different MHLS offices revealed that the offices do not operate with equal degrees of efficiency and timeliness. Providers who worked with the MHLS in the 3rd Department described positive experiences, while those who worked with MHLS in other departments shared less positive experiences.
12. According to some practitioners, certain MHLS departments are already involved in this fashion.
13. *See* NY PHL §2994-a(3). When CPR is so defined, a non-hospital DNR order may not prevent emergency medical services personnel from intubating a patient whose heart was failing if the patient still has some pulse and breathing. A non-hospital DNI order may also need to be issued. *See* PHL §§ 2994-aa(4) and 2994-dd(6).
14. *See* Alvin Moss, et al., *Prognostic Significance of the "Surprise" Question in Cancer Patients*, 13 J Palliative Care 837, 838-839 (2010) (explaining that physicians consistently overestimate when providing specific term survival prognoses for patients with cancer, and that their accuracy significantly improved when answering the question, "would you be surprised if this patient died in the next year?").
15. *See* 14 NYCRR §27.9 (2015) *and* 14 NYCRR §527.8 (2015).
16. *See* 14 NYCRR §633.16 (2015).
17. *See* 14 NYCRR §527.8(c)(1) (2015) &14 NYCRR §633.16 (2015).
18. *See* NY PHL §2994-f(2)(b).

NEWS flash

What's Happening in the Section

Recent Aid in Dying Program to Receive National Award

The recent NYSBA CLE program, *Aid in Dying: A Terminally Ill Patient's Right to Choose and What Practitioners Need to Know*, received the "Award of Outstanding Achievement" from the Association for Continuing Legal Education (ACLE). The award is in the category of "Award of Professional Excellence" and is the top award in this category. It is the first time that an NYSBA program has won in the overall best CLE Program category. The CLE program was originally presented in person on December 16, 2015 in New York City with a simultaneous live webcast, and drew a total of 243 attendees.

Program Co-Chairs Lawrence R. Faulkner and Alice Herb developed "Aid in Dying," along with NYSBA CLE attorney Alex Glick-Kutscha. Lawrence R. Faulkner is Chair-Elect of the Health Law Section, and both he and Alice Herb are past chairs of the Section's Committee on the Ethical Issues in the Provision of Health Care.

The Award was presented on August 2, 2016 to the CLE Department at ACLEA's annual meeting in Seattle, Washington.

Upcoming Events

- **Fall Meeting.** The Section's fall meeting will be held on Friday, October 28, 2016 at the NYSBA Bar Center in Albany New York. The program is under development. Check the NYSBA website for information.

Recent Events

- **E-Health Clinical Records and Data Exchange: Part I.** This program, held on June 28, 2016 at Albany Law School and webcast, explored the state of the industry and the law affecting: Electronic Health Records (EHRs) across provider types and payor systems; integration of Health Information Exchanges (HIEs) and Regional Health Information Organizations (RHIOs), including the State Health Information Network of New York (SHIN-NY); and the changing role of health research and data (including data generation, management and interpretation).

  Speakers included Al Cardillo, Vice President, Home Care Association of New York State (HCA-NYS); Paul Gillan, Esq., Wilson Elser Moskowitz Edelman & Dicker LLP, Albany; Elizabeth Amato, Director, Statewide Services, New York eHealth Collaborative (NYeC); Raul Tabora, Esq., Bond Schoeneck & King, PLLC; Melissa Zambri, Esq., Barclay Damon, Albany, NY.

- **Networking Event at HANYS.** A "Summer Membership Appreciation and Networking Reception" was held on June 2 at the headquarters of the Healthcare Association of NY (HANYS) in East Greenbush, N.Y. The event, which was well attended and enjoyable, was organized by Membership Committee Co-Chairs Karen Gallinari, Esq. and Salvatore Russo, Esq., and by Young Lawyers Committee Co-Chairs Nicole Ozminkowski, Esq. and Lara Glass, Esq.

Section Committees and Chairs

The Health Law Section encourages members to participate in its programs and to volunteer to serve on the Committees listed below. Please contact the Section Officers or Committee Chairs for further information about these Committees.

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