



2021 | VOL. 26 | NO. 2

# Health Law Journal

A Peer Reviewed Law Journal

A publication of the Health Law Section of the New York State Bar Association



Federal Health Care Program  
Exclusion Lists and the  
Employee Screening Process

How Low Can You Go?:  
COVID-19 Crisis Tests Legal  
Parameters of Medicaid  
Reimbursement

Demise of the Treating  
Physician Rule



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# Legal Manual For New York Physicians

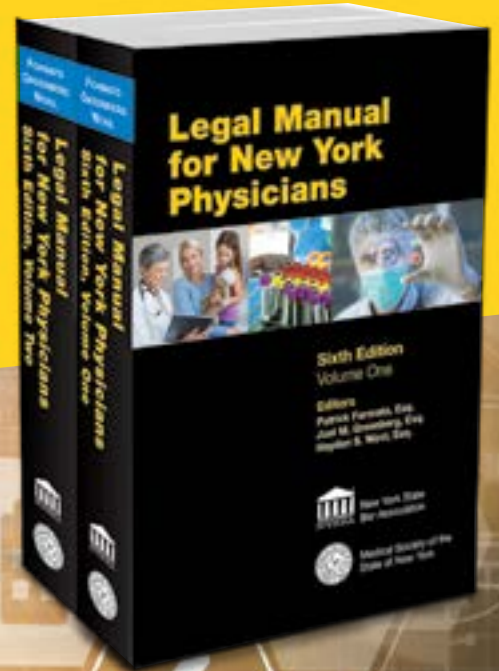
Sixth Edition

**Editors:**

**Patrick Formato, Esq.**

**Joel M. Greenberg, Esq.**

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## Publication and Editorial Policy

Persons interested in writing for this *Journal* are welcomed and encouraged to submit their articles for consideration. Your ideas and comments about the *Journal* are appreciated as are letters to the editor.

### Publication Policy:

All articles should be submitted to:

Brendan S. Parent, J.D.

Email: [brendan.parent@nyu.edu](mailto:brendan.parent@nyu.edu)

Benjamin Sundholm

Email: [bts43@georgetown.edu](mailto:bts43@georgetown.edu)

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## HEALTH LAW JOURNAL

### Editors

Brendan S. Parent  
NYU School of Medicine  
227 E 30th St, Ste 721  
New York, NY 10016  
[brendan.parent@nyu.edu](mailto:brendan.parent@nyu.edu)

Benjamin Sundholm  
Devevoise & Plimpton  
919 3rd Ave  
New York, NY 10022-3902  
[bts43@georgetown.edu](mailto:bts43@georgetown.edu)

### Section Officers

#### Chair

Karen L. Illuzzi Gallinari  
St. John's Riverside Hospital  
Yonkers, NY 10701-1301  
[kgallinari@gmail.com](mailto:kgallinari@gmail.com)

#### Chair-Elect

Anoush K. Scott  
Lippes Mathias Wexler Friedman LLP  
54 State St., Fl 10  
Albany, NY 12207-2540  
[akoroghlianscott@lippes.com](mailto:akoroghlianscott@lippes.com)

#### Vice-Chair

Nathan G. Prystowsky  
Axiom  
16 N Broadway, Apt 2N  
White Plains, NY 10601-2223  
[nprystowsky@icloud.com](mailto:nprystowsky@icloud.com)

#### Treasurer

Jane B. Burke  
Hodgson Russ LLP  
677 Broadway, St 301  
Albany, NY 12207-2986  
[Jbburke@hodgsonruss.com](mailto:Jbburke@hodgsonruss.com)

#### Secretary

Lisa D. Hayes  
The Brookdale Hospital Medical Center  
1 Brookdale Plaza Katz 321  
Brooklyn, NY 11212-3198  
[lhayes@bhmcny.org](mailto:lhayes@bhmcny.org)

## NYSBA.ORG/HEALTH

# Message from the Section Chair

By Karen L. Illuzzi Gallinari



Dear Health Law Section Members,

You would think there are just so many times one should comment upon what a challenging year this has been and continues to be. Nonetheless, the continuing and increasing difficulties our colleagues, communities and neighbors are facing warrants our commitment and perseverance for advocacy. There are many reasons to feel optimistic about the days ahead and happy that our dedication does a lot to help and ease suffering.

This wide range and dichotomy of emotions reminds me why I love health law. Unlike other areas of law, health law is very diversified. The issues health law attorneys address run the gamut from bioethics to criminal law and involve every area of law directly affecting public health and the delivery of health care. Health law attorneys also attend to other legal issues impacting individuals and corporations, such as real estate and taxes. There is a topic to interest everyone and a worthy area for your expertise and energy.

This issue of our *Journal* provides evidence of this variety. The articles include scholarly analysis of and initiatives to address important issues affecting informed consent, long term care, opioids, cannabis, liability, insurance and telehealth. Please join me in thanking our authors, our

*Journal* Editors, Brandon Parent and Benjamin Sundholm, and each of our Health Law Section Committee Chairs. Each of them has provided you and our industry valuable information, resources and reason to know that the state of our society and the laws which support it can improve. Recent discussions with New York State legislative and agency leaders regarding our COVID-19 recommendations demonstrate that our work product and expertise are influential.

Plans are afoot for a special event to celebrate the first opportunity for us to gather together physically. Please stay tuned for details. In the meantime, if you are not yet a member of one of our Committees please do join a Committee. Our Committees and Committee Chairs are listed in the back of this *Journal*. Simply pick one which interests you and contact the Committee Chair/s and Catherine Carl at [ccarl@nysba.org](mailto:ccarl@nysba.org).

My fellow officers and the Committee Chairs look forward to meeting those of you we have not yet had the pleasure to meet. We also welcome those of you interested in leadership opportunities. Become more involved and grow with us.

## NEW YORK STATE BAR ASSOCIATION

If you have written an article you would like considered for publication, or have an idea for one, contact *Health Law Journal* Editors:

Brendan Parent  
212-998-7065

[brendan.parent@nyu.edu](mailto:brendan.parent@nyu.edu)

and

Benjamin Sundholm  
[bts43@georgetown.edu](mailto:bts43@georgetown.edu)

Articles should be submitted in electronic format (pdfs are NOT acceptable), along with biographical information.

# REQUEST FOR ARTICLES



# In the New York State Courts

By Leonard M. Rosenberg

## State Court of Appeals Rules That Providing Criminal Prosecution Powers to Justice Center Special Prosecutor Is Unconstitutional

*People v. Viviani*, 2021 WL1177916 (N.Y., March 30, 2021). As part of the Protection of People with Special Needs Act, Executive Law § 552 created a special prosecutor, appointed by the governor, with the power to investigate and prosecute crimes of abuse or neglect of vulnerable victims in facilities operated, licensed, or certified by the state. In this case, defendants, who were indicted by the special prosecutor for various sex offenses, asserted that the statute is an unconstitutional delegation of prosecutorial authority away from the county district attorney—selected constitutional officers—to an unelected appointee of the governor.

The Special Needs Act created a “Justice Center,” the primary purpose of which would be the protection of vulnerable persons. To further that goal, the Act empowered the Justice Center to investigate reports of abuse and neglect and to conduct disciplinary proceedings for state employees in any instance of substantiated findings. The Justice Center has one unit responsible for prosecution of criminal matters, and one for the resolution of non-criminal matters.

Executive Law § 552 created a new “special prosecutor and inspector general” appointed by the governor, with authority to: (1) “investigate and prosecute” offenses involving abuse or neglect against a vulnerable person by the person’s professional caregiver; and (2) “cooperate with and assist district attorneys and local law enforcement in their efforts against such abuse or neglect of vulnerable persons.” In the Special Needs Act’s prefatory statement, the Legislature expressed its intent to give the Justice Center “concurrent authority with district attorneys to prosecute abuse and neglect crimes committed against such persons.”

Although the special prosecutor may “apply for search warrants,” absent “exigent circumstances,” the special prosecutor is required to give prior notice of the warrant application to the district attorney of the county in which the warrant is to be executed. The special prosecutor also may, after consultation with the district attorney, appear in any grand jury and its attending superior court for the purpose of conducting a criminal action or proceeding concerned with an offense related to abuse or neglect of a vulnerable person. While in court or before the grand jury, the special prosecutor “may exercise

all the powers and perform all the duties in respect of such actions or proceedings which the district attorney would otherwise be authorized or required to exercise or perform.”

The attorney general intervened and maintained that, for the statute to pass constitutional muster, it must be read to allow the special prosecutor to pursue a case only “as a delegate of the County District Attorney’s prosecutorial authority.”

The Court noted that a statute enjoys a strong presumption of constitutionality. A party who seeks to rebut that presumption bears the “heavy burden” of proving beyond a reasonable doubt that the statute is in conflict with the Constitution. The Court framed the question as whether the creation of the special prosecutor takes an essential function from a constitutional officer and gives it to a different officer chosen in a different manner.

Although the Constitution established the elected office of the district attorney, it did not assign prosecutorial authority to any constitutional officer, leaving that matter for the Legislature. The county law accomplishes the task by providing that it is the “duty of every district attorney to conduct all prosecutions for crimes and offenses cognizable by the courts of the county for which [such District Attorney] shall have been elected or appointed” (County Law § 700[1]). Thus, district attorneys “have plenary prosecutorial power in the counties where they are elected.”



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**Leonard M. 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. 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.**

The Court explained that “the essence of a District Attorney’s constitutional, statutory and common-law prosecutorial authority is the ‘discretionary power to determine whom, whether and how to prosecute [in] a criminal matter.’” However, Executive Law § 552 deprives elected district attorneys of an essential function of their constitutional office, i.e., the discretionary power to determine whom, whether and how to prosecute a criminal matter, by vesting concurrent discretionary power in a different, non-elected, officer.

The Court further noted that although it is well settled that “a statute ought normally to be saved by construing it in accord with constitutional requirements, . . . the very language of the statute must be fairly susceptible of such an interpretation; put otherwise, the saving construction must be one which the court ‘may reasonably find implicit’ in the words used by the Legislature.”

The Court pointed out that Executive Law § 552 contains no express requirement that the local district attorney consent to, and retain authority for, the prosecution of the designated crimes. Moreover, in the Special Needs Act’s prefatory statement, the Legislature expressed its intent to afford the special prosecutor and the county district attorneys “concurrent” prosecutorial authority. Section 552 allows the special prosecutor to “exercise all the powers and perform all the duties” that the district attorney “would be authorized or required to exercise or perform,” and adds special prosecutor to the definition of “District Attorney” found in the Criminal Procedure Law (CPL 1.20[32]). The court held that these provisions refute any legislative intent to condition the special prosecutor’s authority on the conduct of the local district attorney.

Although § 552 directs the special prosecutor to give the local District Attorney notice of a search warrant application (Executive Law § 552[2][b]), and to “consult[ ]” with the local district attorney as to the time and place of any appearance before a grand jury or superior court, the court held that clear import of these “modest requirements” is that the special prosecutor must keep the local district attorney informed, not that the special prosecutor must obtain the local district attorney’s permission.

The Court rejected the attorney general’s argument that § 552 could be found constitutional if interpreted to require that the local district attorney retain ultimate responsibility for the prosecution, finding that such interpretation lacks statutory support; the court is “not at liberty to save a statute by, in effect, rewriting it in a manner that contravenes its unambiguously articulated legislative purpose.”

Having ruled unconstitutional the provisions that confer criminal prosecution authority on the special prosecutor, the court considered whether those provisions may be severed and the remainder of the statute preserved. The Court framed this question as “whether the [L]egislature, if partial invalidity [of the statute] had been foreseen,

would have wished the statute to be enforced with the valid part excised, or rejected altogether.”

The Court ruled that as the purpose of the Special Needs Act was to “bolster the ability of the state to respond more effectively to abuse and neglect of vulnerable persons,” the Legislature would wish that as much of Executive Law § 552 as can be preserved remain in effect. The Court also found that nullifying the criminal prosecution provisions would not leave the remainder of the statute without any beneficial impact.

Accordingly, the Court ruled that the provisions of Executive Law § 552 that provide the special prosecutor with authority to engage in non-prosecutorial functions, and to cooperate with and assist district attorneys, should remain in force.

### **The Appellate Division for the Second Department Holds That Physician Policyholders Are Entitled to Receive MLMIC Demutualization Funds**

*Maple Medical, LLP v. Scott*, 191 A.D.3d 81, 138 N.Y.S.3d 61 (2d Dep’t 2020). Plaintiff, a medical practice, brought this and five similar actions against former physician employees and malpractice insurer Medical Liability Mutual Insurance Company (MLMIC) asserting claims for declaratory judgment, breach of contract, unjust enrichment, and failure to comply with the New York Insurance Law, on the basis that the medical practice, and not the defendant-employees, was entitled to the cash consideration generated pursuant to MLMIC’s demutualization.

In 2016, MLMIC announced that National Indemnity Company (NICO), a subsidiary of Berkshire Hathaway, would acquire MLMIC and that, as part of that transaction, MLMIC would be converted or “demutualized” from a mutual insurance company to a stock insurance company. Pursuant to this transaction, MLMIC agreed to distribute certain cash consideration received from NICO, in an amount approximately 1.9 times the sum of premiums that were timely paid during a defined three-year period, to eligible policyholders or their “Designees.”

The disputed funds in *Maple Medical* were generated pursuant to MLMIC malpractice policies by which the defendants were insured during their time as employees of the medical practice. As the policyholders of the policies in question, the employees claimed that they were the proper recipients of the associated cash consideration. The practice disagreed, asserting that since it paid the entirety of the premiums for the policies, it was the proper recipient of the demutualization funds.

The medical practice and each of the employees moved for summary judgment. Finding that it was bound by the Appellate Division for the First Department’s decision in *Schaffer, Schonholz & Drossman, LLP v. Title*, 171 A.D.3d 465, 465, 96 N.Y.S.3d 526 (1st Dep’t 2019), the

Supreme Court, Westchester County, denied the employees' motions and declared that the practice was entitled to the cash consideration.

Joining with the Appellate Division for the Third and Fourth Departments, the Appellate Division for the Second Department reversed the trial court's decision and declared that the employees were the proper recipient of the funds. In reaching this conclusion, the court relied on New York Insurance Law § 7307, which governs how mutual insurance companies convert to stock insurance companies, MLMIC's plan of conversion, and the New York State Department of Financial Services' decision approving MLMIC's demutualization. The court found that these authorities "make clear that the policyholder is entitled to the consideration paid in connection with the MLMIC demutualization," absent an assignment of that right to a policy administrator. Since the documentary evidence established that the defendants were the policyholders for the MLMIC policies and that they had not designated the practice to receive the demutualization proceeds, the court held that the former employees were the proper recipients of the cash consideration.

The court also rejected the practice's contention that its former employees would be unjustly enriched if they were to receive the cash consideration and declined to follow the Appellate Division for the First Department's holding in *Schaffer*. Specifically, the court found that: (1) the employees' receipt of the funds would not be due to a legal or factual mistake, as they are legally entitled to them as the policyholders; and (2) the cash consideration was a windfall to all of the parties, as none of them anticipated its distribution; (3) no party changed position based on the demutualization; and (4) the employees' conduct was neither tortious nor fraudulent.

### **Appellate Division Holds That PHL § 2994 Does Not Grant Family Member Authority To Sign Nursing Home Arbitration Agreement**

*Gayle v. Regeis Care Ctr., LLC*, 191 A.D.3d 598 (1st Dep't 2021). The issue before the Appellate Division, First Department was whether the New York Family Health Care Decisions Act (FHCDA), which is found in New York's Public Health Law § 2994 (PHL), grants a surrogate decision maker the authority to exercise power of attorney over a decedent's affairs, or to execute an Arbitration Agreement on a decedent's behalf.

Plaintiff brought a wrongful death action against Defendant Jewish Home Lifecare (JHL) on behalf of her husband. Specifically, she alleged medical malpractice, wrongful death, and violation of the PHL.

Plaintiff is also the Administratrix of her husband's estate. Prior to decedent's death plaintiff and her adult daughter brought the decedent to JHL nursing home facility. An initial evaluation determined that the decedent had significant cognitive impairments and could neither

legally express his wishes, nor fully understand the legal terms for his admission. Additionally, the decedent had neither a health care proxy, nor an agent pursuant to power of attorney. Consequently, the daughter served as his surrogate decision-maker.

Plaintiff and her daughter received an admission agreement ("Agreement") from JHL. Pursuant to the grant of authority permitted by the FHCDA, the daughter exercised the right to execute the Agreement. The FHCDA authorizes a family member or close friend of a patient to serve as the patient's health care representative when the patient lacks decisional capacity and has no prior instructions regarding their health care wishes. This individual has the authority to make any and all health care decisions on the adult patient's behalf that the patient could make. *See* PHL § 2994-d(1) (3)(i). The Agreement contained an optional arbitration provision that the JHL sought to enforce when plaintiff filed suit.

The Supreme Court, Bronx County, granted JHL's motion to compel arbitration. The Appellate Division noted that under PHL § 2994, the surrogate decision-maker's authority is limited to making decisions regarding any treatment, service or procedure to diagnose or treat the patient's physical or mental condition. Although PHL § 2994 granted the daughter authority to execute the Agreement for purposes of admitting her father into the facility for health care treatment, she did not have authority to execute the arbitration provision on his behalf. The court reasoned that such agreement was entirely optional, had no bearing on the decedent's health care, and this is entirely outside the scope of authority set forth in PHL § 2994.

### **Court Holds That "Wrongful Prolongation of Life" Actions Are Not Cognizable in New York**

*Lanzetta v. Montefiore Medical Center*, 2021 WL 609828 (Sup. Ct. Bronx Cty. 2021). Plaintiff Joseph Lanzetta, as the executor of the estate of his deceased father, Pasquale Lanzetta, brought an action against Montefiore Medical Center and two treating physicians, Dr. Potenza and Dr. Hochster. Plaintiff alleged that defendants disregarded decedent's living will and his health care agent's directive, which specified that the decedent should not be administered life-sustaining treatment. Instead, plaintiff asserted that defendants administered multiple doses of antibiotics and IV fluid to the decedent, extending his life for approximately 20 days. Defendant Hochster sought summary judgment to dismiss the claim against him. Though defendant raised several issues on summary judgment, the court only addressed plaintiff's claim for "wrongful prolongation of life." The Supreme Court, Bronx County, held that such claim is not cognizable under New York statutory or common law, and granted defendant's motion for summary judgment.

"Wrongful life" claims are typically brought by the parent or guardian of an impaired child, based on the theory that this child "would have been better off" if they



had never been born. The court noted that wrongful life actions are not cognizable in New York because such actions offend public policy and “the status of being alive does not constitute an injury in New York.” The court relied on the Court of Appeals’ decision *Becker v. Schwartz*, 46 N.Y. 2d 401 (1978).

The court also relied on the Second Department’s decision in *Cronin v. Jamaica Hosp. Med. Ctr.*, 60 A.D.3d 803 (2009). In *Cronin*, plaintiff sought damages on behalf of decedent, who was alleged to have been resuscitated twice, despite having do-not-resuscitate orders in place. The Second Department held that the claim, which has been characterized as one for wrongful prolongation of life, was essentially a “wrongful life” action and could not be sustained.

Next, the court analyzed plaintiff’s claims of tort liability under two provisions of the Public Health Law. First, plaintiff alleges liability under Public Health Law § 2982. Under this law, a health care provider must comply in good faith with a patient’s health care agent’s decisions. The court noted that this law does not create an express private right of action against a health care provider, and considered whether an implied private right of action can be ascertained from the statute. The three factors for evaluating the implication of a private right of action include “(1) whether the plaintiff is one of the class for whose particular benefit the statute was enacted; (2) whether recognition of a private right of action would promote the legislative purpose; and (3) whether creation of such a right would be consistent with the legislative scheme.” The court held that plaintiff satisfied the first two factors, but an implied private right of action would be inconsistent with the legislative scheme. Discussing the legislative history of Public Health Law § 2982, the court noted that neither the law’s sponsor nor Governor Cuomo “suggested in their respective legislative memoranda that a damages action was an appropriate remedy for a health care provider’s failure to honor a health care agent’s directives, which failure prolonged a patient’s life.” This, combined with New York’s common law stance that “being alive [does] not constitute an injury,” led the court to conclude that an implied private right of action did not exist.

Second, the court addressed plaintiff’s argument that defendants were liable under Public Health Law § 2994-f, which is part of the Family Health Care Decisions Act (FHCDA). Section 2994 provides a procedure for the selection of a surrogate health care decision-maker. The court held that the FHCDA was inapplicable to the case because the decedent, by way of a living will, had designated a health care agent. The court explained that pursuant to Public Health Law § 2994-b, the FHCDA does not apply where a patient has a duly appointed health care agent. The court concluded that although New York law recognizes an individual’s right to have one’s medical treatment wishes honored, it does not recognize a cause of action for wrongful prolongation of life, and that



the decision to do so lies with the appellate courts or the Legislature.

### Third Department Rejects Constitutional Challenge to Measles Vaccine Mandate

*F.F. v. State*, 2021 WL 1032935 (3d Dep’t Mar. 18, 2021). As a prerequisite to attending a school or child care facility, Section 2164 of the New York Public Health Law requires children between two months and 18 years old to be immunized from certain diseases, including measles. Until 2019, this mandate had only two limited exceptions: a medical exemption (requiring a physician’s certification that a certain vaccine may be detrimental to a child’s health) and a religious exemption (requiring a statement by a parent/guardian that he or she objects to vaccination on religious grounds). In June 2019, in response to a measles outbreak centered in Brooklyn and Rockland County, the New York State Legislature repealed the religious exemption.

In *F.F.*, a group of parents whose children had previously been granted religious exemptions, sought to enjoin the repeal and have it declared unconstitutional. The state moved to dismiss for failure to state a claim, and the Supreme Court, Albany County, granted the motion in its entirety—finding that plaintiffs failed to allege any cognizable constitutional claims. On appeal, plaintiffs raised a number of constitutional challenges, but primarily argued that the repeal was motivated by active hostility toward religion, in violation of the Free Exercise Clause.

Before proceeding to the merits, the court was tasked with determining the appropriate standard of review, and confronted the following question: given that the repeal eliminated a religious exemption, is it nonetheless a neutral law of general applicability? Plaintiffs advanced three arguments in support of their position that it was not: (1) the Legislature failed to act during the height of the outbreak, and the timing of the repeal undermines its purported public health rationale; (2) the Legislature failed to hold public hearings on the issue; and (3) statements made

by certain legislators reveal an underlying animus toward religion. The court addressed each argument in turn.

First, with respect to timing, the court found that the repeal “simply worked its way through the basic legislative process, and was motivated by a prescient public health concern.” In support of this conclusion, the court noted that the American Medical Association, the Medical Society of the State of New York, the American Academy of Pediatrics, and the New York State American Academy of Pediatrics, as *amici curiae* in support of the state’s position, uniformly concluded that the repeal was a “sound, evidence-based decision in the interest of public health.” Thus, despite the approximate nine-month delay between the height of the outbreak and the repeal, the court found that the Legislature’s response “reveal[ed] a reasonably prompt deliberation and targeted response to a very serious public health issue.”

Second, the court rejected plaintiffs’ claims regarding the failure to hold public hearings. In doing so, the court noted the Legislature’s reliance on scientifically accurate data from various medical experts—including the *amici* and the CDC—and cited the “spirited floor debate” among legislators. The court was also persuaded that opponents of the repeal received a fair opportunity to be heard, observing that the Legislature received “several hundred letters . . . mostly in opposition to the repeal, which address[ed] religious issues.”

Third, the court rejected plaintiffs’ claims of religious animus among legislators. In particular, the court observed that the handful of alleged statements suggesting religious hostility “were attributed to only 5 of the over 200 legislators in office at any given time” and were not sufficient to “taint the actions of the whole.” Further, the court found that some of the alleged statements were not indicative of religious animus at all, but rather expressions of concern that the religious exemption may be susceptible to abuse by individuals seeking to evade the vaccination requirement for non-religious reasons.

Having rejected these arguments, the court determined that the repeal was indeed a law of general applicability: “[i]n fact, the sole purpose of the repeal is to make the vaccine requirement generally applicable to the public at large in order to achieve herd immunity.” Against this backdrop, the court ruled that the repeal was “not based upon hostility toward religion” and “given the significant public health concern, the repeal is supported by a rational basis and does not violate the Free Exercise Clause.”

The court also rejected plaintiffs’ claims under the New York Constitution, the Equal Protection Clause, and the Freedom of Speech Clause—holding that plaintiffs failed to establish an “unreasonable interference” with religious freedom, failed to establish that the repeal “makes classifications based on religion” (rather, it merely “places all school-aged children who are not medically exempt on equal footing”), and failed to establish that the repeal “in-

terferes with their rights of free speech . . . as the conduct allegedly compelled is not sufficiently expressive to trigger First Amendment protections.” Accordingly, the court affirmed the Supreme Court’s order dismissing plaintiffs’ complaint in its entirety.

### **Federal District Court Dismisses Constitutional Challenges to Department of Health Orders Excluding Unvaccinated Students From Schools During Measles Outbreak**

*W.D. v. Rockland County*, 2021 WL 707065 (S.D.N.Y. 2021). Plaintiffs, the parents of unvaccinated students at the Green Meadow Waldorf School and the Otto Spect School (collectively, GMWS), filed this lawsuit against the Rockland County Health Department (RCDOH or the “Department”), challenging the constitutionality of Department actions during the measles outbreak. As measles cases increased in Rockland County—particularly amongst children—during the fall of 2018, the Department took several actions to prevent the spread of measles and promote public health. On October 17, 2018, the RCDOH began requiring schools with confirmed cases to temporarily exclude from attendance students that could not provide proof of vaccination, including students who had religious or medical exemptions. As cases continued to rise, the RCDOH expanded the order to include schools that did not have cases, but had low vaccination rates and were close in geographic proximity to schools that had positive measles cases. Notably, many of these schools were in geographic proximity to Hasidic Jewish communities.

On December 3, 2018, the Department ordered GMWS to exclude all non-vaccinated students from school, despite not having any confirmed measles cases, due to its location and its low vaccination rate. The court refers to this as the “First Exclusion Order.” Though GMWS is not a religious school, the school’s entire population of non-vaccinated students had a religious exemption. On December 21, 2018, the RCDOH raised the required vaccination rate to 95%, and informed GMSW that this exclusion order would be lifted if GMWS could meet this threshold. The court refers to this as the “Second Exclusion Order.” On January 30, 2019, the RCDOH found that the GMSW high school had done so, and lifted the exclusion order. However, the elementary school did not, and the order remained in place. Plaintiffs alleged that, with respect to the elementary schools, a Third Exclusion Order was issued February 7, 2019, and GMSW was informed that the order would not be lifted until a 95% vaccination rate was reached or 42 days had passed without any new cases. In March 2019, an Emergency Declaration was issued, which prohibited unvaccinated children from places of public assembly, including schools. Though this Declaration did not apply to children with medical exemptions, it applied to children with religious exemptions and those unvaccinated for any other reason. Plaintiffs sought a preliminary injunction through an Article 78 hearing seeking repeal of the Emergency Declaration and the Third Exclusion Or-

der. The preliminary injunction was granted and affirmed on appeal. Plaintiffs then filed this lawsuit alleging violation of procedural due process, the Free Exercise Clause, the Equal Protection Clause, and plaintiffs' First Amendment freedom of assembly rights. Defendants moved for summary judgment on each of these claims.

First, Plaintiffs argued that the Exclusion Orders and Emergency Declaration deprived their children of the "state created right to send their children to school without vaccinations" without affording adequate process, in violation of the Fourteenth Amendment. The court conducted separate analyses for the Exclusion Orders and the Emergency Declaration. First, the court held that, with respect to the Exclusion Orders, plaintiffs' claim failed as a matter of law. The court found that no property or liberty interest that was protected by the Due Process Clause was asserted. The court delved into an examination of the "plain language" of all the New York laws plaintiff argued created a property interest in a parent's right to not vaccinate their child. The court held that the discretionary language of these statutes, which afforded the Commissioner of Health the discretion to exclude unvaccinated children from certain settings during an outbreak, cut against the existence of a property interest.

The court also determined that, even assuming the existence of a constitutionally protected interest, plaintiffs failed to raise a triable issue of fact as to whether the process received through the Article 78 hearing was adequate. The court noted that the Supreme Court of the United States has held that procedural due process can be satisfied by a "meaningful" post-deprivation remedy in instances of an "emergency." The Supreme Court has defined an emergency as a "situation in which swift governmental action is necessary to protect the public health and safety." In instances where an emergency is present, the court is required to determine (1) whether the defendants' emergency action was exercised in an arbitrary manner; and (2) a meaningful post deprivation remedy was available to the Plaintiffs." Finding that defendants reasonably believed an emergency existed at the time of each Exclusion Order, the court held that the defendants did not act arbitrarily when issuing the Exclusion Orders. The court then held, relying on Second Circuit decisions, that the Article 78 proceeding was an adequate emergency post-deprivation remedy.

The court then discussed the Emergency Declaration and whether it violated procedural due process. The court again determined that plaintiffs "neither stated a viable property interest in sending their children to school without vaccination at the time of the Declaration, nor raised a triable issue of fact as to whether issuance of the Declaration constituted an abuse of discretion." The court found that the language of the Executive Law afforded the commissioner the discretion to determine whether unvaccinated children should be sent to school, and found that, under the scope of the Executive Law, a "public health

emergency" or "disaster" was taking place. Notably, the court disagreed with the Rockland County Superior Court's decision to grant the injunction revoking the Emergency Declaration and the Third Exclusion Order. The Rockland County Superior Court had consulted two dictionary definitions of the word "epidemic," the second of which defines an epidemic as an adjective, "affecting or tending to affect a disproportionately large number of individuals within a population, community, or region at the same time." Holding that the number of cases "did not rise to the level of an epidemic" and "did not affect a disproportionately large number of individuals within the population of the County at the same time," the court sided with plaintiffs and ordered that the children be permitted to attend school. The court opined that the Rockland County Supreme Court incorrectly relied on the adjective definition of epidemic and found that, instead, it should have relied on the noun definition of epidemic, as it is used in the New York Executive Law. As a noun, an epidemic is defined as "an outbreak of disease that spreads quickly and affects many individuals at the same time." Finding that, under this definition, an "epidemic" and therefore a "disaster" was occurring, the Emergency Declaration was permissible. Finally, the court again held that the Article 78 proceeding that plaintiffs were afforded was an adequate emergency post-deprivation remedy.

Second, the court addressed Plaintiffs' Free Exercise Clause argument that the Emergency Declaration "intentionally targeted persons with sincerely-held religious beliefs" by barring children with religious exemptions, but not medical exemptions, from public places. The court held that since the law was facially neutral and generally applicable, a rational basis review applied, and that under such review, the Declaration served the legitimate government purpose of protecting the community. The court found that the Declaration did not explicitly target religious practice, nor did it describe the categories of affected person in terms of their religion, because it applied to children who were unvaccinated "for *any* reason," except those with documented medical exemptions. Finally, the Declaration did not create harsher penalties or "single out" certain groups for engaging in religious conduct. This rationale also motivated the court's finding that the law is generally applicable because it imposes identical burdens on religious and non-religious conduct. Next, the court held that the Declaration was rationally related to the defendants' stated interest in controlling the measles outbreak given the medical evidence submitted regarding the risk of transmission during large gatherings, and that unvaccinated children were most likely to become sick from the measles. The court opined that even if it were to review the Declaration under a strict scrutiny standard, it would survive this review, because the defendants' interest in containing the measles outbreak was "compelling" and the Declaration was narrowly tailored and the least restrictive means to achieve containing the outbreak.

Third, the court turned to plaintiffs' allegation that the Emergency Declaration violated the Fourteenth Amendment Equal Protection Clause by treating their children differently with respect to both their religion and their age. With respect to discrimination based on religion, the court held that the Declaration was rationally related to its stated public health purpose, despite treating children with religious exemptions different from children with medical exemptions and vaccinated children. Next, the court addressed plaintiffs' argument that the Declaration violated the Equal Protection Clause because it failed to restrict unvaccinated adults. Defendants note that imposing such restrictions on unvaccinated adults would be harmful to the community, as those adults would be unable to work, earn income, and care for their families. Noting other court decisions which have held that the Equal Protection Clause was not violated where an age-based distinction served for the protection or promotion of another age group, the court found that this precise circumstance was applicable to the measles outbreak.

Finally, the court addressed plaintiffs' claim that the Declaration, without a legitimate purpose, violated their children's right to assemble publicly. Plaintiffs argue that this right was restricted because there was no "immediate threat to public safety, peace or order" at the time the Declaration was issued. The court noted that a state can permissibly restrict First Amendment activity for the benefit of public health, so long as it does not differentiate religious and secular activities that impose similar risks. The court held that the Declaration was a "content-neutral" restriction on public assembly because it restricts assembly not on the basis of the religion of the people gathering, but by the size of the gathering itself. Second, the regulation prohibits unvaccinated children from entering *any* public place of assembly—not just houses of worship or places for religious functions. Finally, the court noted that the affected children were left open "ample alternative channels for communication," since children could still gather in smaller groups or gather in a private residence, and the Declaration carved out exceptions for children to gather in larger numbers where required by law or for medical treatment. The court found that the gathering restrictions supported a significant government interest in curbing the outbreak, were narrowly tailored, and were not "substantially broader than necessary."

### **Appellate Division Holds That There Is No Private Right of Action for Violation of Article 11 of the Social Services Law**

*Joseph v. Nyack Hospital*, 191 A.D.3d 1, 136 N.Y.S.3d 404 (2d Dep't, 2020). Infant plaintiff, by his mother, sued Nyack Hospital, the Medical-Dental Staff of Nyack Hospital, Nyack Hospital Foundation, Inc., and Michael Levy ("defendants") to recover damages for personal injuries allegedly sustained by the infant plaintiff, a special needs individual, at a hospital. The plaintiffs asserted, *inter alia*, two causes of action for violations of Social Services

Law Article 11, which alleged that defendants committed physical abuse and deliberate inappropriate use of physical restraints as defined in Social Services Law § 493(4)(b).

Plaintiffs moved for summary judgment on the issue of liability on these causes of action and the defendants cross-moved for judgment dismissing these claims. The trial court denied the plaintiff's motion and granted dismissal of plaintiffs' claims related to violations of Social Services Law Article 11. The trial court concluded that creating a private right of action under the statute would be inconsistent with the legislative scheme.

The Appellate Division noted that in the absence of such an express private right of action, plaintiffs can seek civil relief in a plenary action based on a violation of a statute only if a legislative intent to create such a right of action is fairly implied in the statutory provisions and their legislative history. It is for the courts to determine what the legislature intended.

The Court of Appeals has consistently identified three essential factors to be considered in determining whether a private right of action can be fairly implied from the statutory text and legislative history: (1) whether the plaintiff is one of the class for whose particular benefit the statute was enacted; (2) whether recognition of a private right of action would promote the legislative purpose; and (3) whether creation of such a right would be consistent with the legislative scheme. All three factors must be satisfied before a court will recognize an implied private right of action. However, the third factor has been recognized as the most important as the Legislature has both the right and the authority to select the methods by which its goals are effectuated, and to choose the goals themselves. Consequently, courts have declined to recognize a private right of action in instances where the Legislature specifically considered and expressly provided for enforcement mechanisms in a statute itself.

The Appellate Division held that there is no private right of action for alleged violations of Article 11 of the Social Service Law. The court noted that Social Services Law Article 11 was enacted to create a set of uniform safeguards to bolster the protection of people with special needs in New York. To implement those safeguards, the New York State Justice Center for the Protection of People with Special Needs was established, which was empowered to receive, investigate, and respond to allegations of abuse, neglect or other reportable incidents involving disabled residents receiving services in licensed facilities or provider agencies. The Justice Center is further empowered to implement corrective action plans to prevent future incidents of abuse and neglect.

The court also looked to Social Services Law § 493, entitled "Abuse and Neglect Findings and Consequences," the specific section of Article 11 that plaintiffs referenced in their complaint, which details the possible findings and consequences in connection with an investigation

of abuse or neglect allegations. Following an investigation, a finding must be made, based on a preponderance of the evidence, that the allegation is substantiated or unsubstantiated. Various enumerated consequences are triggered in the event of a substantiated report of abuse or neglect. Specifically, subdivision (4) establishes four categories of substantiated reports based on the nature and severity of the offending conduct and/or the facility conditions. Those categorizations, in turn, trigger corresponding consequences, which may include disciplinary action, prevention and remediation requirements, and/or state agency oversight.

Article 11 also sets forth a procedure for amendments to and appeals of reports of abuse or neglect, including a hearing at which the Justice Center bears the burden of proving by a preponderance of the evidence that the subject committed the act or acts of abuse or neglect. A Justice Center determination adopting an administrative law judge's decision that the subject committed abuse or neglect is further subject to review by way of a proceeding pursuant to CPLR Article 78. The Justice Center must maintain a register of individuals against whom a category one case of abuse or neglect has been found to be substantiated.

The court determined that based on its analysis of Article 11 of the Social Services Law, the Legislature had already considered how best to implement its intent and provided the avenues for relief it deemed warranted, by inclusion of the substantial enforcement mechanisms contained within the statute. Examples of these enforcement mechanisms include, the maintenance of the Justice Center; the delineation of possible findings and consequences in connection with an investigation; procedures for amending and appealing substantiated abuse or neglect reports; and the maintenance of a register of subjects found to have a substantiated category one abuse or neglect case. The court found that creating a private right of action for an alleged violation of the statute would be inconsistent with the legislative scheme. Thus, a private right of action may not be fairly implied, regardless of whether the plaintiffs are of the class for whose particular benefit the statute was enacted, and regardless of whether recognition of a private right of action would promote the legislative purpose.

### **Citing COVID-19 Pandemic, Bronx Supreme Court Compels Remote Deposition**

*Rodriguez v. Montefiore Med. Ctr.*, 70 Misc.3d 991, 139 N.Y.S.3d 510, (Sup. Ct. Bronx Cty., Dec. 23, 2020). In *Rodriguez*, the Supreme Court of Bronx County confronted an issue that has plagued trial courts throughout the state since COVID struck: whether parties may be compelled to conduct remote depositions. Citing the “unprecedented public health circumstances occasioned by the coronavirus pandemic,” the court answered this question in the affirmative.

Plaintiff commenced the action in February 2019, claiming negligence and medical malpractice on behalf of her decedent. During a January 29, 2020 court conference, the parties stipulated that dates for the various party depositions would be set at the next discovery conference, scheduled for March 18, 2020. Given the onset of the pandemic, that conference never took place.

In the ensuing months, plaintiff's counsel attempted to schedule her client for a remote deposition, but the defendants declined to proceed. In response, plaintiff moved to compel a remote deposition, citing CPLR 3103, along with various orders issued by the Chief Administrative Judge, a number of unreported trial court decisions and orders, and several federal court decisions. Defendants opposed the motion, maintaining that a remote deposition would give plaintiff's counsel an opportunity to “coach” her client inappropriately, and would curtail defense counsel's ability to evaluate the witness' demeanor and candor.

The court first acknowledged the general rule, under CPLR 3110 and 3113, that depositions will take place in person absent a stipulation to the contrary. Still, the court found that the rule is “not rigid” insofar as CPLR 3103(a) permits a court to condition or regulate the use of “any disclosure device,” including depositions. Moreover, the court cited a series of pre-pandemic cases and publications—dating back to 2004—for the proposition that a court has discretionary power to compel a remote deposition over a party's objection. Of course, the court acknowledged that the case law on this issue was sparse, “reflecting the infrequency with which parties sought to compel remote depositions.”

During the pandemic, however, “that which was once extraordinary has become routine.” Citing a line of recent cases, mostly from trial courts in counties throughout the state, the court found it well-established that “the personal and public health dangers posed by the coronavirus pandemic present an undue hardship” sufficient to justify compulsion of a remote deposition. The court also found such compulsion consistent with the “spirit” of various orders issued by the Chief Administrative Judge of the Courts, and consistent with CPLR 104 (“The [CPLR] shall be liberally construed to secure the just, speedy, and inexpensive determination of every civil judicial proceeding.”) Thus, the court held that “appearances for in-person depositions would present an undue hardship, and [the] depositions ought to be conducted remotely.”

To assuage defendants' concerns, the court fashioned various safeguards aimed at protecting the integrity of the deposition: (1) only plaintiff's counsel and/or a court reporter are permitted to be in the same room as plaintiff; (2) plaintiff is prohibited from communicating with anyone not participating in the deposition; (3) communications between plaintiff and her counsel during the deposition are limited to subjects appropriate under 22 N.Y.C.R.R. Part 221; (4) prior to initiating any private communications with his or her client, plaintiff's counsel must

first announce their intention to do so; and (5) plaintiff and her counsel must be visible on screen at all times. At the same time, the court acknowledged defendants' contention that "counsel's assessment of a deponent's credibility is an important component of the litigation process," but countered that "[a] remote deposition is a virtue in this regard, because it allows a deponent to testify without a mask . . . [which] could not occur at an in-person deposition during a pandemic." Similarly, the court observed that "given the state of technology used to facilitate and conduct remote depositions (and on-going improvements thereto), counsel should have a reasonable opportunity to evaluate the credibility of a deponent."

Finally, in a likely sign of things to come, the court remarked that "a party's apprehension concerning innovative discovery techniques must, subject to the various protections afforded by the law, yield to the realities of coronavirus-era litigation, lest resolution of litigants' rights and obligations be unnecessarily and unjustly delayed."

### **Third Department Holds That The Administrative Law Judge and Hearing Committee of Committee of the State Board for Professional Medical Conduct Have Discretion To Relieve Physician of Default in Answering Professional Misconduct Charges**

*Offor v. Zucker*, 185 A.D. 3d 1187 (3d Dep't, 2020). In *Offor v. Zucker*, the Third Department held that the Administrative Review Board for Professional Medical Conduct (ARB) had the discretionary authority to relieve a physician of a default in answering charges of professional misconduct under Public Health Law § 230(10)(c)(2).

Under Public Health Law § 230(10)(c)(2), a physician charged with professional misconduct by the Bureau of Professional Medical Conduct (BPMC) must file a written answer to each of its charges and allegations 10 days prior to an administrative hearing or those charges and allegations will be deemed admitted.

In 2017, the BPMC charged the petitioner with 11 specifications of misconduct arising from her treatment of four patients between August 2012 and June 2014. The BPMC alleged that petitioner deviated from accepted standards of medical care by providing inappropriate and untimely diagnoses and treatments, failing to order necessary specialist consultation, using contraindicated medications, and failing to maintain records that accurately reflected the care and treatment she rendered to those patients.

The BPMC served the petitioner with a notice of hearing on December 22, 2017, setting the date for her administrative hearing on January 25, 2018. On January 19, 2018, Petitioner retained a new attorney, who immediately requested an adjournment to allow time to prepare. The BPMC objected, and the Hearing Committee of the State Board for Professional Medical Conduct denied counsel's request.

On January 23, 2018, two days before petitioner's administrative hearing was to begin, she filed her answer to the BPMC's charges. However, at a pre-hearing conference held on January 24, 2018, the Administrative Law judge presiding over the hearing refused to accept Petitioner's answer since it was filed less than 10 days before the hearing, explaining that there was "no remedy here in this forum for addressing that." As such, the ALJ deemed the BPMC's charges admitted under operation of law pursuant to Public Health Law § 230(10)(c)(2). Consequently, at the commencement of petitioner's hearing, the ALJ refused to accept Petitioner's proffered answer, and the Hearing Committee, considering only what penalty to impose on petitioner, voted to revoke her medical license. The petitioner appealed to the ARB, which affirmed the Hearing Committee's determination.

The petitioner then commenced an Article 78 proceeding seeking to annul the ARB's decision, arguing that she was arbitrarily denied the right to file an answer and was improperly deemed to have admitted the BPMC's charges. Respondents countered by arguing that since Petitioner failed to present a reasonable excuse for her default, the ARB's determination deeming the charges admitted should be upheld.

In annulling the ARB's determination, the court held that Public Health Law § 230(10)(c)(2) did not impose such a bar. The court noted that the statutory language mandating the timely filing of an answer was added to Public Health Law § 230(10)(c)(2) in 1996, and prior to that, the filing of such an answer was discretionary. According to the court, the legislative history indicated that the 1996 amendment's purpose was to expedite professional misconduct proceedings by focusing on matters only in dispute.

Given this legislative framework, the court determined that allowing a physician to submit an answer prior to their hearing date would not compromise this statutory objective. The court also identified a prior decision, *Tribeca Med., P.C. v. New York State Dept. of Health*, 83 A.D. 3d 1135 (3d Dep't 2011), in which it held that the ARB possessed the discretionary authority to relieve a licensee of a default in answering professional misconduct charges. Accordingly, the court held that the ALJ and the Hearing Committee had the discretionary authority to accept the petitioner's answer filed after the 10-day deadline, but prior to the administrative hearing.

The court determined that both the ALJ and Hearing Committee failed to exercise *any* discretion in rejecting the Petitioner's answer and simply concluded that they lacked the authority to do so as a matter of law. The court also recognized that the ARB incorrectly declined to even address the issue as a procedural matter for the ALJ to resolve. Those errors, according to the court, rendered the ARB's determination arbitrary and capricious.

### Third Department Holds That Physician Charged With Misconduct in Referral Proceeding Has No Right to Interview

*In re Ogundu v. Dept. of Health*, 188 A.D. 3d 1469 (3d Dep't 2020). The petitioner in this case, a physician licensed to practice medicine in New York, sought review of the Administrative Review Board's (ARB) revocation of her medical license, contending, among other arguments, that (1) the Office of Professional Medical Conduct (OPMC) was obligated to offer her the opportunity to be interviewed during its investigatory process, (2) that the ARB improperly rejected her invocation of Corrections Law article 23-A, (3) that the ARB's revocation of her medical license was an abuse of discretion, and (4) that the ARB was not empowered to issue its determination beyond the 45-day period specified in the Public Health Law. The Third Department rejected all of Petitioner's arguments and upheld the revocation of her medical license.

Following an indictment on numerous offenses arising out of an alleged scheme to defraud local, state, and federal governments out of grant monies awarded to her not-for-profit corporation, petitioner was convicted at a jury trial of 29 felony counts. As a result, the Commissioner of Health summarily ordered petitioner to cease practicing medicine. Simultaneously, the Bureau of Professional Medical Conduct (BPMC) commenced a direct referral proceeding, charging Petitioner with professional misconduct based on her felony convictions. The charges against petitioner were sustained following an administrative hearing, and the Hearing Committee of the State Board for Professional Medical Conduct suspended petitioner's medical license for one year and placed her on probation for three years.

The petitioner and BPMC both cross-appealed the Hearing Committee's determination to the Administrative Review Board for Professional Medical Conduct. The ARB overturned the Hearing Committee's penalty, and revoked petitioner's medical license.

Petitioner then commenced an Article 78 proceeding in the Supreme Court, Queens County, seeking to annul the commissioner's summary order and the ARB's revocation of her medical license. The Supreme Court observed that the only issues appropriately raised by petitioner were those involving the ARB's determination, and transferred the matter to the Third Department.

Upon review of the summary order, the Third Department found that the commissioner's summary order expired as a result of the determination issued by the Hearing Committee and then modified by the ARB. As a result, the court held that petitioner's contentions regarding the order were moot.

The court also observed that it was unclear whether petitioner, who proceeded pro se, was challenging the decision of the Hearing Committee, or ARB's ultimate

determination. Regardless, the court held that since the petitioner appealed the Hearing Committee's decision to the ARB, its review was limited to whether the ARB's determination was arbitrary and capricious, affected by error of law, or an abuse of discretion.

With respect to petitioner's first argument, the court held that she was incorrect in asserting OPMC was obligated to offer her an opportunity to be interviewed during its investigatory process. A licensee must be offered an investigatory interview in cases where the OPMC has looked into the physician's suspected professional misconduct and referred the matter to an investigation committee for further review. The court contrasted such a situation with petitioner's, as an investigation committee was not involved, and the professional misconduct charges against her were the result of her criminal convictions. Those convictions were directly referred to the Hearing Committee for an expedited hearing limited only to the nature and severity of the penalty to be imposed. The court further held that petitioner was not entitled to an interview as a matter of due process, because an interview would do little in the context of a direct referral proceeding, beyond affording her an opportunity to relitigate the circumstances underlying her criminal convictions.

The court next considered petitioner's second argument, that the ARB improperly rejected her attempt to invoke the protections of Corrections Law article 23-A. The court rejected this argument as well, finding that Corrections Law was designed to eliminate bias against ex-offenders in obtaining employment or licenses, and had no bearing on petitioner's disciplinary proceeding, as she already possessed a medical license. The court was similarly unpersuaded by petitioner's contention that her receipt of a certificate of relief from disabilities arising out of her convictions prevented the ARB from exercising its discretionary power to revoke her medical license.

Third, the court determined that the ARB's revocation of petitioner's medical license was not an abuse of discretion. In particular, the court noted that petitioner's convictions concerned her misappropriation of hundreds of thousands of dollars in funds from local, state, and federal governments over several years. The court also took issue with petitioner's downplaying of her crimes, as well as her lack of remorse for them. While petitioner's crimes did not directly cause patient harm and she had provided beneficial services to the community, the court nevertheless held that due to her lack of integrity revealed by her betrayal of the public trust, it was unable to hold that the ARB's revocation of her medical license was so disproportionate to the offense that it shocked one's sense of fairness.

Finally, the court held that petitioner's remaining contentions, including her argument that the ARB was powerless to issue its determination beyond the 45-day period set forth in Public Health Law § 230-c(4), was without merit.

# COVID-19, Nursing Homes and the Legislative Response

James W. Lytle

In response to concerns over the impact of COVID-19 on the residents of nursing homes in New York, a substantial amount of attention and effort will be devoted during the course of the 2021 Legislative Session to issues relating to the state's current approach to the oversight, regulation, and reimbursement of skilled nursing facilities and adult care facilities.

**Background:** The impact of COVID-19 on nursing homes should not have been surprising. The very first COVID-19 cases that arose in the U.S. were identified in a skilled nursing facility in the State of Washington and the pandemic has, as of early March 2021, resulted in the deaths of approximately 15,000 New Yorkers in nursing homes and adult care facilities throughout the state.<sup>1</sup> Part of the concern over these issues was the lack of clarity, almost from the outset of the pandemic, as to what the death toll actually was within these long term care facilities.<sup>2</sup>

As COVID-19 began its fatal rampage, nursing home administrators and staff complained to state officials over the lack of PPE and other resources to combat the pandemic, but were, at least initially, told that assembling protective equipment was their responsibility. In late April, Governor Andrew Cuomo asked the Department of Health and the Attorney General to investigate whether nursing homes "were following the rules" as they confronted the spread of COVID-19.<sup>3</sup>

Nine months later, in late January 2021, the New York State Attorney General Letitia James released her report on the investigation. Among other findings, the Attorney General's preliminary analysis found that the Department of Health had undercounted deaths of nursing home residents due to COVID-19 by about 50%, largely because the state (contrary to other states' practices) did not count the deaths of those residents who were transferred to hospitals immediately prior to their deaths.<sup>4</sup> Shortly after the report was issued, a court ruling was issued that ordered the Department to release the nursing home fatality data that it had declined to release since last summer.<sup>5</sup>

Apart from the controversy or confusion over the nursing home mortality data, the Attorney General's report went far beyond merely reigniting that controversy. Among other things, the report found:

- widespread non-compliance with infection control protocols;

- an apparent relationship between lower Centers for Medicare and Medicaid Services (CMS) staffing ratings and a higher death rate, leading the Attorney General to recommend enactment of mandated staffing ratios;
- the unavailability of PPE and testing during the early days of the pandemic put residents and staff at increased risk; and
- the failure by nursing homes to comply with requirements relating to communication with family members caused unnecessary distress.<sup>6</sup>



Moreover, the report responded to another early policy controversy. A March 25 policy directive precluded nursing homes from denying re-admission or admission of individuals based on a confirmed or suspected diagnosis of COVID-19—a policy that some feared might exacerbate the risks to nursing home patients. The policy was subsequently rescinded by the Department of Health on May 10.

State officials strongly rejected the suggestion that the mandate on COVID-19 admissions had any adverse impact on nursing homes in a report that the Administration issued last July, which attributed the spread of COVID-19 in nursing homes to community spread of the disease and contrasted New York's nursing home death numbers to the experience of other states. Recent reports have suggested that the July report had been significantly rewritten and edited by the governor's top aides, allegedly over the objections of Department of Health officials.<sup>7</sup> The attorney general's report, for its part, did not rule out the possibility that the March 25 admission mandate policy could have resulted in more deaths: "While additional data and analysis would be required to ascertain the effect of such admissions in individual facilities, these admissions may have contributed to increased risk of nursing home resident infection, and subsequent fatalities."<sup>8</sup>

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





**Governor's Legislative Proposals:** To address these issues and their considerable political fallout, the governor advanced a series of proposals as part of his 30-day budget amendments, contained within part GG of the Health and Mental Hygiene Article VII legislation. Those legislative initiatives include proposals that would:

- **Increase fines and civil penalties for violations of Public Health Law** from \$2,000 to \$10,000 for an initial violation, up to \$15,000 for subsequent violations and up to \$25,000 if the violation results in serious physical harm to patients. In addition, the provisions authorize the use of amounts collected pursuant to these penalty provisions, to improve quality of care through enhanced surveillance and inspection activities and other quality improvement strategies.
- **Impose new reporting requirements** for residential health care facilities to include information relating to “staffing, the source of staffing, and staff skill mix” (but without mandating staffing ratios).
- **Require facilities to contract with quality improvement organizations** if they receive more than one statement of deficiencies relating to infection control practices and policies.
- **Establish new “excess revenue” requirements** on residential health care facilities that would require a minimum of 70% of revenue be spent on direct resident care and at least 40% devoted to “resident-facing staffing” and would require facilities not meeting these amounts to repay the state any excess amounts.
- **Impose executive and managerial salary caps**, subject to regulation by the Department of Health, with a cap on compensation at no more than \$250,000, and limit overall expenditure on executive or managerial salaries at no more than 15%.
- **Require posting** of key information relating to nursing homes, including the maximum rates for facilities and services on the facility’s website, the owners of the facility, the facility’s landlord and any contracts for the provision of goods or services for the facility.
- **Increase penalties for adult care facilities** under the Social Services Law, similar to those noted above for DOH-regulated facilities, and changes rectification opportunities for facilities otherwise liable for civil penalties for violations.
- **Allow appointment of a temporary operator for adult care facilities** without requiring that condi-

tions “seriously” endanger the life, health or safety of occupants.

- **Authorize the appointment of emergency receivers for residential health care facilities** “upon a determination that public health or safety is in imminent danger or that there exists any condition or practice or a continuing pattern of conditions or practices that poses imminent danger to the health or safety of any patient or resident of such facilities.”

Given the controversy over the Administration’s handling of these issues, it is not, at this point, clear that the governor’s nursing home package will be ultimately accepted by the Legislature—where both houses have their own ideas of what might be done to address the issue—but the governor has indicated that he will not agree to a state budget that does not contain these new provisions.

**Legislature response:** Both houses of the Legislature have already introduced and even passed a number of proposals addressing nursing homes and adult care facilities, prodded by the current controversy.

The following bills have already passed both houses but have not yet been delivered to the governor:

- **Publication of Nursing Home Ratings** (S.553 Sanders/A.2037 Dinowitz) that requires that the most recent Center for Medicare and Medicaid Services (CMS) rating of every nursing home be prominently displayed on the home page of the Department of Health’s website and at each nursing home facility’s website.
- **Reimagining Long-Term Care Task Force** (S.598B May/A.3922-A Cruz) would be established to study the state of both home-based and facility-based long-term care services in the state, and to make recommendations on potential models of improvement to long-term care services for older New Yorkers.
- **Allowing Compassionate Care-Giving Visitors** (S.614B May/A.1052B Bronson) would create a standardized program to allow personal care and compassionate care visitation by family members and legal guardians that satisfy certain requirements.
- **Quality Assurance Committees** (S.1784A Skoufis/A.5846 Kim) would require adult care facilities to create quality assurance committees that would be integrated into their quality assurance plans.
- **Requirements for Transfer, Discharge and Voluntary Discharge** (S.3058 Rivera/A.3919 Hevesi) would establish requirements for the transfer, discharge and voluntary discharge of residents from residential health care facilities, including provisions that limit discharges to certain circumstances and additional requirements relating to appropriate transfers/discharges.

- **Transparency of Violations** (S.3185 Skoufis/A.5848 Wallace) would require residential health care facilities, as part of the admissions process, to disclose to potential residents and their family members the website where a list of violations and other actions taken against the facility can be found.

The following bills remain pending but have not yet passed both houses:

- **Repeal of Emergency or Disaster Treatment Protection Act** (A.3397 Kim/S.5177 Biaggi), including provisions that had provided some immunity from liability for actions taken during the COVID-19 pandemic emergency.
- **Patient Care Ratio Reporting** (S.4336A Rivera) that would require nursing homes to report on direct patient care expenditures and a host of other categories of expenses and mandate that at least 70% of aggregate revenue to be devoted to direct care of residents.
- **Long-Term Care Ombudsman Program Reform Act** (S.612A May and A5436-A Clark (a similar but not identical bill)) that would expand the current program to be more accessible and available to seniors and their families, while promoting the volunteer advocate program, and would improve interactions between DOH and the ombudsman program regarding complaints.
- **Infection Inspection Audit** (S.1783 Skoufis/A.1999A Gottfried) would direct the Department of Health to establish and implement an infection control inspection audit and checklist for residential health care facilities.
- **Ban on new for-profit nursing homes** (S.5269 Rivera/A.5842 Gottfried) would preclude the CON approval to establish, incorporate or approve the construction of any nursing home that is owned or operated, in whole or in part, by a for-profit entity, while allowing the approval of projects relating to existing for-profit entities that do not result in increased resident capacity.
- **Heightened CON Review for Ownership of Nursing Homes** (S.4893 Rivera) would enhance review of ownership of nursing homes through the certificate of need process, including consideration of past violations at other facilities by owners, and would mandate more public notice within the CON process.
- **Reporting of COVID-19, Communicable Diseases and Deaths** (S.3061A Rivera) would require the Department of Health to record COVID-19 deaths of nursing home residents that died in hospitals to be recorded as nursing home deaths and would require the Department of Health to update and share

data it receives with hospitals and nursing homes on communicable diseases.

- **Requiring negative COVID-19 test results for readmission to nursing homes** (A750 Rosenthal).
- **Inspection Results for Residential Health Care Facilities** (A 1010-A Bronson) would be made publicly available by the Department of Health during the COVID-19 emergency.
- **Nursing home resident COVID-19 testing** (S.1177 May/A.2218 Jacobson) would be required by regulations issued by the health commissioner.
- **Mandatory Reporting of Abuse, Mistreatment or Neglect** (A2420 Aubry) for residents of assisted living and adult care facilities
- **Notice of closure of nursing homes** (A2432 Niou/S. 2847 Kavanagh) would be required ninety days pre-closure.
- **Allows Nursing Home Residents to Designate “Essential Persons”** (A.3113 Kim) who would be permitted access to the nursing home both during and after the COVID-19 emergency to serve as an advocate for the patient.
- **Temporary State Commission on COVID-19 Pandemic Response** (S.2067 Tedisco/A.3162 Kim) to investigate the effects of that response on deaths in nursing homes.
- **Electronic Monitoring Device Authorization** (A3708 Gunther) to allow nursing home patients to install a video or audio recording devices in their rooms under certain circumstances.
- **Nursing home patient trust funds** (A3771 Dickens) would be subject to quarterly audits with reports of such audits provided to the health commissioner.
- **Strengthened oversight of nursing homes in CON process** (A5684A Gottfried) by requiring residential health care facility providers’ applications for changes of ownership to be reviewed and approved based on quality metrics and by mandating notification to the department of certain contractual agreements relating to the operations of the facility.
- **Resident care spending** (A5685 Gottfried), defined to include direct nursing care, support and program services, laundry, food service and other services and programs, would be required to comprise at least 70% of nursing home spending in 2022, increasing to 80% in 2023 and 90% thereafter.
- **Antimicrobial Resistance Prevention and Education Act** (S.2191 Kavanagh/A.5847 Woerner) would require every hospital and nursing home to implement an antimicrobial stewardship program in accordance with federal and state requirements.

- **Health Emergency Response Data System (HERDS)** (A.244 Gottfried) would be established to collect information relating to public health emergencies, which would be made available to governmental entities, health providers and the public, subject to protections of confidential, individually identifiable information.

As this issue was going to print, the Legislature passed legislation that addressed “safe staffing” levels at both hospitals and nursing homes. The hospital-related legislation mandates clinical staffing committees in hospitals to establish staffing plans, but without prescribed staffing ratios. The nursing home legislation actually establishes staffing levels that provide, as of January 1, 2022, at least 3.5 hours of care per resident per day by a certified nurse aide, a licensed nurse or a nurse aide.

Beyond the bills noted above that more specifically relate to the nursing home/long-term care controversy, legislation (S.5357 Stewart-Cousins/A.5967 Heastie) has been passed by both houses and already signed by the governor (Chapter 71 of the Laws of 2021), which will modify the governor’s emergency authority during the pandemic by: allowing existing directives to remain in place for 30 days, subject to a detailed certification of their importance to addressing the emergency; permitting the extension or modifications of directives subject to certain notice requirements and an explanation for the need for the extension/modification; requiring the posting of these directives on a website in an accessible, searchable format; and authorizing the Legislature to terminate any executive orders issued under these provisions and to terminate the state disaster emergency by concurrent resolution.

It should be anticipated that issues relating to the pandemic, generally, and to nursing homes severely impacted by it will continue to occupy the attention of legislators in Albany for the balance of the 2021 legislative session.

## Endnotes

1. *NY officials removed fuller tally of nursing home deaths*, Associated Press, March 6, 2021, <https://apnews.com/article/reports-ny-officials-altered-count-nursing-homes-death-58b0f62d0f88328e911d0d5c65bbf7fe>.
2. Goodman, J. and Hakim, D., *Cuomo Aides Rewrote Nursing Home Report to Hide Higher Death Toll*, New York Times, March 7, 2021.
3. A. Santiago, *NY launches probe into nursing homes*, City & State, April 24, 2020, <https://www.cityandstateny.com/articles/politics/news-politics/ny-launches-probe-nursing-homes.html>.
4. New York State Office of the Attorney General Letitia James, *Nursing Home Response to COVID-19 Pandemic*, January, 2021.
5. *Empire Center for Public Policy v. New York State Department of Health*, Index No. 906023-20 (Albany Co. Supreme Court, February 3, 2021), Justice Kimberly O’Connor.
6. *Nursing Home Response to COVID-19 Pandemic*, *supra* at pp. 48-51.
7. *See Cuomo Aides Rewrote Nursing Home Report to Hide Higher Death Toll*, *supra*.
8. “Nursing Home Response to COVID-19 Pandemic,” *supra* at p. 37.

# In the New York State Agencies

By Francis J. Serbaroli and Caroline B. Brancatella

*\*In light of the COVID-19 emergency, the "In the New York Agencies" column has been on hiatus since March 2020. This issue's column resumes summarizing agency activities affecting health care as of January 2021.*

## **Minimum Standards for Form, Content, and Sale of Health Insurance, Including Standards of Full and Fair Disclosure**

Notice of Emergency Rulemaking. The Department of Financial Services added section 52.76(b) of Title 11 to require immediate coverage, without cost-sharing, for COVID-19 immunizations and the administration thereof. Filing Date: December 16, 2020. Effective Date: December 16, 2020. *See* N.Y. Register January 6, 2021.

## **Crisis Intervention Services for Individuals with Intellectual/ Developmental Disabilities**

Notice of Adoption. The Office for People With Developmental Disabilities added Subpart 635-16 to Title 14 N.Y.C.R.R. to specify qualifications for providers for the provision of these services and allowance for billing. Filing Date: December 22, 2020. Effective Date: January 6, 2021. *See* N.Y. Register January 6, 2021.

## **Consumer Directed Personal Assistance Program Reimbursement**

Notice of Adoption. The Department of Health amended section 505.28 of Title 18 N.Y.C.R.R. to establish a program to pay home care services and establish a methodology framework for the payment of FI administrative costs. Filing Date: December 24, 2020. Effective Date: January 13, 2021. *See* N.Y. Register January 13, 2021.

## **Medical Consent**

Notice of Emergency/Proposed Rulemaking. The Office for People With Developmental Disabilities amended section 633.11 of Title 14 N.Y.C.R.R. to assist providers in administering the COVID-19 vaccine. Filing Date: December 29, 2020. Effective Date: December 29, 2020. *See* N.Y. Register January 13, 2021.

## **Rules Governing the Procedures for Adjudicatory Proceedings Before the Department of Financial Services**

Notice of Emergency Rulemaking. The Department of Financial Services amended Part 2 of Title 23 N.Y.C.R.R. to specify that the Department of Financial Services may conduct administrative hearings by videoconference. Filing Date: January 5, 2021. Effective Date: January 5, 2021. *See* N.Y. Register January 20, 2021.

## **Prohibition of Fireworks**

Notice of Emergency Rulemaking. The Department of Health added Subpart 9-4 to Title 10 N.Y.C.R.R. to prohibit

the use of fireworks. Filing Date: December 30, 2020. Effective Date: December 30, 2020. *See* N.Y. Register January 20, 2021.

## **Prohibition on the Sale of Electronic Liquids with Characterizing Flavors**

Notice of Expiration. The proposed rulemaking in the NYS Register titled "Prohibition on the Sale of Electronic Liquids with Characterizing Flavors" published on December 31, 2019 has expired as of January 2, 2021 and cannot be reconsidered unless the Department of Health publishes a new notice of proposed rulemaking in the NYS Register. *See* N.Y. Register January 20, 2021.

## **General Service Standards Applicable to Outpatient Substance Use Disorder Programs**

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services amended Part 822 of Title 14 N.Y.C.R.R. to set-forth the minimum regulatory requirements for certified outpatient substance use disorder treatment programs. Filing Date: January 12, 2021. Effective Date: January 21, 2021. *See* N.Y. Register January 27, 2021.

## **Principle-Based Reserving**

Notice of Emergency Rulemaking. The Department of Financial Services amended Part 103 (Regulation 213) of Title 11 N.Y.C.R.R. to prescribe minimum principle-based valuation standards. Filing Date: January 11, 2021. Effective Date: January 11, 2021. *See* N.Y. Register January 27, 2021.

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Francis J. 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.

Caroline B. Brancatella is of counsel in the Health & FDA Business Group of Greenberg Traurig's Albany office, where she focuses her practice on health care issues, including regulatory, contracting, transactional, and compliance matters. Prior to joining the firm, she clerked for the Honorable Cynthia M. Rufe of the Eastern District of Pennsylvania.

## **Minimum Standards for Form, Content, and Sale of Health Insurance, Including Standards of Full and Fair Disclosure**

Notice of Emergency Rulemaking. The Department of Financial Services added section 52.16(q) to Title 11 N.Y.C.R.R. to waive cost-sharing for in-network telehealth services. Filing Date: January 7, 2021. Effective Date: January 7, 2021. *See* N.Y. Register January 27, 2021.

## **Personal Care Services (PCS) and Consumer Directed Personal Assistance Program (CDPAP)**

Notice of Revised Rulemaking. The Department of Health revised sections 505.14, 505.28 of Title 18 N.Y.C.R.R. to implement a revised assessment process and eligibility criteria for PCS and CDPAP. *See* N.Y. Register January 27, 2021.

## **Replacement of an Outdated Term**

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services added Part 824 to Title 14 N.Y.C.R.R. to replace the outdated term “chemical dependence” with “addiction services.” Filing Date: January 14, 2021. Effective Date: February 3, 2021. *See* N.Y. Register February 3, 2021.

## **Hospital Personal Protective Equipment (PPE) Requirements**

Notice of Emergency Rulemaking. The Department of Health amended section 405.11 of Title 10 N.Y.C.R.R. to ensure that all general hospitals maintain a 90-day supply of PPE during the COVID-19 emergency. Filing Date: January 15, 2021. Effective Date: January 15, 2021. *See* N.Y. Register February 3, 2021.

## **Nursing Home Personal Protective Equipment (PPE) Requirements**

Notice of Emergency Rulemaking. The Department of Health amended section 415.19 of Title 10 N.Y.C.R.R. to ensure that all nursing homes maintain a 90-day supply of PPE during the COVID-19 emergency. Filing Date: January 15, 2021. Effective Date: January 15, 2021. *See* N.Y. Register February 3, 2021.

## **Reduce Hospital Capital Rate Add-on and Reduce Hospital Capital Reconciliation Payment**

Notice of Adoption. The Department of Health amended section 86-1.25 of Title 10 N.Y.C.R.R. to reduce Hospital Capital Rate Add-on and Reduce Hospital Capital Reconciliation Payment. Filing Date: January 20, 2021. Effective Date: February 3, 2021. *See* N.Y. Register February 3, 2021.

## **Ingredient Disclosures for Vapor Products and E-Cigarettes**

Notice of Proposed Rulemaking. The Department of Health proposed amending Part 1006 to Title 10 N.Y.C.R.R. to provide for enhanced public awareness of

the chemicals used in vapor products and electronic cigarettes. *See* N.Y. Register February 3, 2021.

## **Minimum Standards for Form, Content, and Sale of Health Insurance, Including Standards of Full and Fair Disclosure**

Notice of Emergency Rulemaking. The Department of Financial Services amended Part 52 (Regulation 62) of Title 11 N.Y.C.R.R. to waive copayments, coinsurance, and annual deductibles for essential workers for in-network outpatient mental health services. Filing Date: January 26, 2021. Effective Date: January 26, 2021. *See* N.Y. Register February 10, 2021.

## **Meeting Space in Transitional Adult Homes**

Notice of Emergency Rulemaking. The Department of Health amended section 487.13 of Title 18 N.Y.C.R.R. to establish criteria for suitable meeting space to ensure privacy in conversations and submit a compliance plan to the Department. Filing Date: January 21, 2021. Effective Date: January 21, 2021. *See* N.Y. Register February 10, 2021.

## **Hospital Indigent Care Pool Payment Methodology**

Notice of Adoption. The Department of Health amended section 86-1.47 of Title 10 N.Y.C.R.R. to develop an indigent care distribution methodology for calendar years through 2022. Filing Date: January 29, 2021. Effective Date: February 10, 2021. *See* N.Y. Register February 10, 2021.

## **Name Change for the Physically Handicapped Children's Program (PHCP)**

Notice of Proposed Rulemaking. The Department of Health proposed amending Parts 11, 46 and 85 of Title 10 N.Y.C.R.R. to change the name of the PHCP to Children and Youth with Special Health Care Needs Support Services Programs. *See* N.Y. Register February 10, 2021.

## **Erratum**

The Department of Health corrected a notice of emergency rulemaking relating to Nursing Home Personal Protective Equipment (PPE) Requirements published in the February 3, 2021 issue of the State Register. It inadvertently contained a typographical error in the purpose of the rule making. The original purpose read “To ensure that all nursing homes maintain a 90-day supply of PPE during the COVID-19 emergency”; the corrected purpose is “To ensure that all nursing homes maintain a 60-day supply of PPE during the COVID-19 emergency.” *See* N.Y. Register February 17, 2021.

## **Surge and Flex Health Coordination System**

Notice of Emergency Rulemaking. The Department of Health added sections 1.2, 700.5, Part 360; amended sections 400.1, 405.24, 1001.6 of Title 10 N.Y.C.R.R.; and amended sections 487.3, 488.3 and 490.3 of Title 18 N.Y.C.R.R. to provide authority to the commissioner to direct certain actions and waive certain regulations in an

emergency. Filing Date: February 1, 2021. Effective Date: February 1, 2021. *See* N.Y. Register February 17, 2021.

### **Rate Setting for Residential Habilitation in Community Residences and for Non-State Providers of Day Habilitation**

Notice of Proposed Rulemaking. The Department of Health proposed amending Subpart 86-10 of Title 10 N.Y.C.R.R. to amend rate methodologies limiting payments to IRA providers to conform to provisions in approved waiver. *See* N.Y. Register February 17, 2021.

### **Reimbursement of Waiver Services**

Notice of Proposed Rulemaking. The Office for People With Developmental Disabilities proposed amending sections 635-4.4, 635-10.4, Subpart 641-1 of Title 14 N.Y.C.R.R. to conform OPWDD waiver services to the federally approved waiver agreement. *See* N.Y. Register February 17, 2021.

### **Revise Requirements for Collection of Blood Components**

Notice of Emergency Adoption and Revised Rulemaking. The Department of Health amended Subpart 58-2 of Title 10 N.Y.C.R.R. to facilitate the availability of human blood components while maintaining safety. Filing Date: February 5, 2021. Effective Date: February 5, 2021. *See* N.Y. Register February 24, 2021.

### **Notice to Employees Concerning Termination of Group and Health Insurance Policies, Etc.**

Notice of Proposed Rulemaking. The Department of Financial Services proposed amending Parts 55 (Regulation 78), 62 (Regulation 96), 89 (Regulation 118), 136 (Regulation 85), 216 (Regulation 64), 218 (Regulation 90); repealing Subpart 65-3 (Regulation 68-C), Appendix 13; and adding new Subpart 65-3 (Regulation 68-C), Appen-

dix 13 to Title 11 N.Y.C.R.R. to make technical changes; comport with statutes; update office addresses; correct citations; etc. *See* N.Y. Register March 3, 2021.

### **Hospital Non-Comparable Ambulance Acute Rate Add-On**

Notice of Emergency Rulemaking. The Department of Health amended section 86-1.15 of Title 10 N.Y.C.R.R. to prevent duplicate claiming by Article 28 hospitals for the ambulance add-on regarding participation in the program. Filing Date: February 16, 2021. Effective Date: February 16, 2021. *See* N.Y. Register March 3, 2021.

### **Surrogacy Programs and Assisted Reproduction Service Providers**

Notice of Emergency/Proposed Rulemaking. The Department of Health added Subpart 69-11 to Title 10 N.Y.C.R.R. to license and regulate surrogacy programs. Filing Date: February 16, 2021. Effective Date: February 16, 2021. *See* N.Y. Register March 3, 2021.

### **Redesigning Residential Treatment Facilities (RTF)**

Notice of Emergency/Proposed Rulemaking. The Office of Mental Health repealed Part 583 and amended Part 584 of Title 14 N.Y.C.R.R. to provide clarity and provide uniformity relating to RTF's and to implement chapter 58 of the Laws of 2020. Filing Date: February 10, 2021. Effective Date: February 10, 2021. *See* N.Y. Register March 3, 2021.

### **Day Habilitation Duration**

Notice of Emergency Rulemaking. The Office for People With Developmental Disabilities amended section 635-10.5 of Title 14 N.Y.C.R.R. to assist providers in maintaining capacity to operate during the public health emergency. Filing Date: February 10, 2021. Effective Date: February 10, 2021. *See* N.Y. Register March 3, 2021.



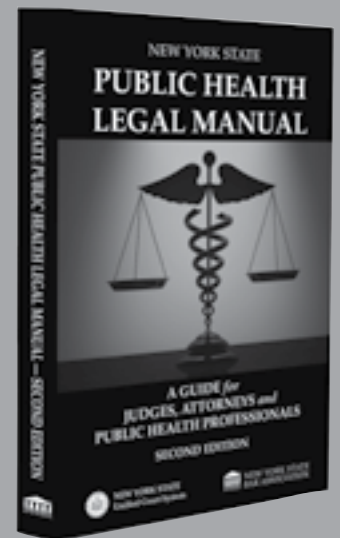


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# New York State Fraud, Abuse, and Compliance Developments

Edited by Melissa M. Zambri

## New York State Department of Health Medicaid Decisions<sup>1</sup>

Compiled by Margaret M. Surowka

### Northern Metropolitan RHCF, Inc. (Decision after Hearing November 19, 2020, John Harris Terepka, ALJ)

Appellant, Northern Metropolitan RHCF, is a 12-bed residential health care facility (RHCF) located in Monsey, New York. The RHCF is licensed pursuant to Article 28 of the Public Health Law, and is enrolled as a Medicaid Provider. This matter involved an audit reviewing Appellant's reimbursement for Medicaid recipients who were residents of Northern Metropolitan RHCF from June 1, 2010 through August 31, 2012. The audit was conducted by Health Management Systems, Inc. (HMS), the New York State Office of the Medicaid Inspector General's (OMIG's) contracted agent. Appellant contested only one of the three categories of disallowances: Medicaid reimbursement paid without being reduced by partial or full net available monthly income (NAMI), totaling \$15,475.22 with interest in the amount of \$1,192.93. As an initial matter, the administrative law judge (ALJ) rejected appellant's arguments based on *Concourse Rehabilitation & Nursing Center, Inc. v. Shah*, 161 A.D.3d 669 (1st Dep't 2018), *lv. denied*, 32 N.Y.3d 904 (2018). ALJ Terepka dismissed Appellant's reading of the *Concourse* case stating that the issues in the audit hearing were not tried in *Concourse*, and as such the case offered no support for the assertion that a Medicaid claims audit is the appropriate forum to address a "bad debt" argument or other issues relating to reimbursement rates.

Turning to the audit findings, there was no showing that the claims appellant submitted to the Medicaid Program were reduced by the residents' NAMI. The ALJ further clarified that it is the facility's responsibility to collect the NAMI, and that the Medicaid program should not be charged regardless of whether the facility is able to collect the NAMI amount. ALJ Terepka stated: "It is the nursing home's responsibility to collect that NAMI from the resident. The facility is not entitled to turn to the Medicaid Program to make good its loss if the resident does not pay it." (Decision at 9). Appellant's argument was also rejected based on failure of proof and a complete lack of legal support. In so holding, the ALJ analyzed the decision in *Eden Park Health Services, Inc. v. Axelrod*, 114 A.D.2d 721 (3d Dep't 1985), and noted that a claims audit is not the appropriate forum to argue for the recognition of uncollected NAMI as a reimbursable cost in a rate calculation.

Appellant's argument that interest was improperly calculated from the date of the payment, rather than the date the Final Audit Report was issued, similarly confused cost reports with audits of claims. Pursuant to 18 N.Y.C.R.R. § 518.4(b), in a claims audit, interest is charged from the time of the overpayment, and instead, interest is only calculated 90 days after the Final Audit Report in audits of



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Melissa M. Zambri is the managing partner of the Albany Office of Barclay Damon, LLP and the Co-Chair of the Firm's Health Care and Human Services Practice Area, focusing her practice on enterprise development and regulatory guidance for the health care industry. She also teaches Legal Aspects of Health Care for Clarkson University and is an Adjunct Professor at Albany Law School.

Margaret M. Surowka is counsel to Barclay Damon, LLP in its Albany Office, focusing her practice on health care law, advising health care providers on federal and state statutory and regulatory compliance, and representing health care providers in response to audits, investigations and disciplinary matters.

Mary Connolly is an associate attorney at Barclay Damon LLP in its Albany office, concentrating her legal practice on representing health care providers in a variety of matters including health care-related litigation, arbitration, and audits, as well as regulatory, compliance, and transactional matters.

Bridget Steele is an associate attorney at Barclay Damon, LLP in its Rochester office, focusing her practice on health care law, including assisting organizations with regulatory and compliance matters.

Dena DeFazio is an associate attorney at Barclay Damon LLP in its Albany office, focusing her practice on the health care and human services industry, including regulatory and compliance matters. DeFazio also has a M.S.W. from the University at Buffalo.

Jennifer Cruz is a law clerk at Barclay Damon LLP in its Albany office, focusing her practice in the health care and human services and health care controversies areas.



claims reports. As such, the ALJ affirmed OMIG's determination as to both overpayments and interest.

### **Kiddin' Around Town, Inc. (Decision after Hearing November 19, 2020, Kimberley A. O'Brien, ALJ)**

Appellant, Kiddin' Around Town, Inc., was enrolled as provider of transportation services in the New York State Medicaid Program. OMIG issued a Draft Audit Report for services provided from March 1, 2012 through December 31, 2015, which was part of a large "system match audit" of many transportation providers. The audit consisted of a computer review of the data for every claim made by appellant during the audit period for 4 categories of disallowances. Appellant was cited for two of the four categories of disallowances: that there were unqualified or disqualified drivers totaling \$365,001.50 in payments, and that there were incorrect or missing vehicle license plates for the dates of service totaling \$44,666.05, resulting in a total overpayment of \$410,146.74.

In response to the Draft Audit Report, appellant simply argued that the errors were administrative errors, and that all of the services at issue were provided. No documentation was submitted in response to the Draft Audit Report. Thereafter, appellant did provide a spreadsheet of driver names, dates of the services provided, and the driver license numbers. At hearing, appellant acknowledged that the driver's license number on the claims were entered in error and that they were no longer employed at the time of service. The spreadsheet appellant provided indicated that other drivers should have been entered on the claim forms. Appellant did not produce appropriate contemporaneous documentation including valid driver's license documentation for each of the disallowed claims, as required.

As to the missing license information, appellant admitted that they had failed to enter the information because they thought the claim was for a livery ride and therefore, did not require the information. Again, appellant failed to produce any of the required information for each of the claims. As such, OMIG's determination as to the overpayment was affirmed, with interest.

### **Madison York Assisted Living Community (Decision after Hearing October 30, 2020, Natalie J. Bordeaux, ALJ)**

Appellant, Madison York Assisted Living Community, is a Medicaid enrolled Assisted Living Program (ALP). OMIG conducted an audit through the New York City Human Resources Administration (HRA) for Medicaid claims for ALP services from January 1, 2009 through December 31, 2011. After the issuance of the Final Audit Report, OMIG agreed to withdraw certain disallowances and the total sample disallowance amount was reduced to \$2,047.94 which was extrapolated for a total overpayment amount of \$3,483,353.47.

The main contested finding was in the category of Missing Service Documentation, and related to documentation that was destroyed following flooding caused by Superstorm Sandy. The 22 disallowed claims in this category involved dates of service ranging from December 27, 2008 through June 4, 2009, for which claims were paid between the six-month period of January 1, 2009 through June 30, 2009. No findings were made in this category for claims paid during the remaining 30 months of the audit period. Appellant consistently contended that supporting documentation for the disallowed claims had been destroyed during Superstorm Sandy, which struck the New York City area on October 29, 2012. Appellant asserted that its building experienced significant flooding in both the basement and boiler room, and that many items stored there, including service documentation (aide activity sheets and toileting sheets) for 2007, 2008, and the first six months of 2009 "were destroyed and not salvageable." (Decision at 9). Appellant submitted an insurance claim and received reimbursement for the damages sustained.

After advising the auditors that the required service documentation for these claims was destroyed during the storm, appellant attempted to address the auditors' requests by providing the information that was available for each sampled claim, including census data to show that a resident was in the building on the date of service, plans of care, and payroll records for staff who were assigned to provide assistance to those residents. OMIG took the position that appellant was required to report the destruction of these records to the Department of Health (DOH), and to attempt to salvage its wet medical records. OMIG relied on a DOH Advisory dated November 8, 2012 (issued 10 days after Super Storm Sandy), addressed to "Physicians and Other Medical Practitioners" requiring providers to get verification that the records had been rendered unusable, unreadable, or indecipherable before it destroyed them. Although the advisory recommends various means by which to save "wet medical records," it did not require providers to report disposal of unsalvageable documents. (Decision at 13).

The ALJ found OMIG's insistence on evidence that the discarded documentation was unsalvageable was not supported by any applicable legal requirement in effect from October 29, 2012 through November 7, 2012. Nor was there any requirement in effect from October 29, 2012 through April 30, 2015 requiring appellant to notify DOH of its disposal of soaked, soiled, illegible, and utterly destroyed documentation. DOH did not issue blanket instructions pertaining to all Medicaid providers on how to report unexpected damage, loss, or destruction of records until May of 2015. The newsletter issued in May of 2015 was followed by a "Dear Administrator Letter" addressed to ALPs dated June 3, 2015, which "required ALP operators to maintain both documentation and evidence of the destruction." (Decision at 14). This requirement was nearly three years after appellant's destroyed documents were discarded, more than six months after the audit



began, and after appellant had already communicated its problems with providing the required service documentation to the auditors.

The ALJ also found that the auditors failed to completely follow guidance regarding destroyed documents that was in effect before, during, and in the nine days after the storm, specifically Division of Medicaid Audit Directive No. 23 dated June 24, 2010. By the standards imposed in the directive, appellant's inability to produce documentation for 22 sampled claims, or 22% of those audited, would not justify a termination of the audit. However, the missing documentation for 22 claims in one category encompassing dates of service limited to six months within the entire audit period should have prompted the auditors to:

[A]scertain the circumstances surrounding the destruction of the records. Timely independent Third Party [sic] confirmation should be obtained (i.e. - police reports, fire reports; required notification to DOH, OMH, OMRDD, State Board of Pharmacy regarding timely notice of premature destruction of records; insurance claims, bills for plumbing or repair work, etc.)[.] Any written documentation regarding the flood/fire/event must be obtained and made part of the audit work paper file. [(Decision at 15).]

In spite of this directive, the supporting documentation offered by appellant was ignored, and the auditors did not request any additional information. No claims outside of this six-month period were found to be missing required service documentation, even though several claims sampled pertained to the same resident on different dates of service. The credible, consistent testimony of appellant's witnesses, the clear evidence that appellant repeatedly advised OMIG that records were destroyed during storm-related flooding, the lack of evidence to suggest that the records would have been inadequate had they not been destroyed, and the fact that no legal requirement existed obligating appellant to notify OMIG or any other unit within DOH on the date upon which these records were discarded, met appellant's burden of proving that the disallowances in the category should be reversed.

As to appellant's challenge to the statistical sampling methodology, including the production of an expert witness, the ALJ found appellant's argument lacking, and as such, concluded that appellant had failed to overcome the presumption of validity afforded to the statistical sampling methodology employed by OMIG for extrapolating its audit findings, which was certified to be valid. *See* 18 N.Y.C.R.R. § 519.18(g). As such, OMIG's finding based on Missing Service Documentation was reversed, but the disallowances for Missing Signature on Medical Evaluation and Missing Nursing/Functional/Social Assessment, as well as the extrapolation method used to compute the overpayment amount, were affirmed.

## New York State Attorney General Press Releases

Compiled by Mary Connolly, Jennifer Cruz, Dena DeFazio and Bridget Steele<sup>2</sup>

***Attorney General James Delivers More Than \$573 Million to Communities Across the Nation to Fight Opioid Crisis***—February 4, 2021—Attorney General (AG) James co-lead a coalition of attorneys general in a multi-state opioid agreement addressing the nation-wide opioid crisis. An agreement and consent judgment with McKinsey & Company (“McKinsey”)—filed simultaneously on February 4, 2021 by 47 states, the District of Columbia, and five U.S. territories—resolved investigations by various attorneys general into the consulting company’s role in helping various companies promote their drugs and profiting millions of dollars from the opioid epidemic. A complaint laying out how McKinsey helped Purdue Pharma target doctors they knew would overprescribe opioids, targeted high-volume opioid prescribers, and circumvented pharmacy restrictions to deliver high-dose prescriptions was filed with the agreement. Acting in concert, McKinsey, Purdue, and the Sacklers sold millions of doses of Purdue’s opioids in New York in violation of New York law. Under the terms of the agreement, McKinsey agreed to end the alleged illegal conduct and deliver more than \$573 million into communities across the nation to abate the effects of excessive opioid use. More than \$32 million will go to New York State. In addition, McKinsey agreed to release internal documents detailing its work for OxyContin manufacturer Purdue Pharma, and other opioid manufacturers, for public disclosure online, and to stop advising companies on potentially dangerous opioid-based Schedule II and III narcotics. <https://ag.ny.gov/press-release/2021/attorney-general-james-delivers-more-573-million-communities-across-nation-fight>.

***Attorney General James Releases Report on Nursing Homes’ Response to COVID-19***—January 28, 2021—AG James released a report on her office’s ongoing investigations into nursing homes’ responses to the Novel Coronavirus Disease 2019 (COVID-19) pandemic and allegations of patient neglect. The Office of the Attorney General (OAG) received various complaints and allegations of COVID-19 related neglect of residents at various nursing homes throughout New York, and is currently conducting investigations into more than 20 nursing homes across the State. The report includes preliminary findings showing that a larger number of nursing home residents died from COVID-19 than nursing home data published by DOH reflected, and that the data may have been undercounted by as much as 50%. The OAG also found that nursing homes failed to comply with infection control protocols, had insufficient personal protective equipment for nursing home staff which put residents at increased risk of harm, failed to conduct sufficient COVID-19 testing for residents, and failed to isolate and quarantine residents who tested positive for COVID-19 from the general population. In response to these findings, AG James has recom-

mended eliminating the immunity provisions granted to health care professionals by Governor Andrew M. Cuomo pursuant to the Emergency Disaster Treatment Protection Act (EDTPA). EDTPA provides immunity to health care professionals for potential liability arising from or relating to care of individuals during the COVID-19 pandemic. <https://ag.ny.gov/press-release/2021/attorney-general-james-releases-report-nursing-homes-response-covid-19>.

***Attorney General James Opens Investigation Into ParCare Over COVID-19 Vaccine Distribution***—December 28, 2020—AG James released a statement that her office is launching an investigation into ParCare Community Health Network’s (“ParCare”) distribution of COVID-19 vaccines in New York. The investigation surrounds allegations that ParCare wrongfully distributed and administered COVID-19 vaccines. <https://ag.ny.gov/press-release/2020/attorney-general-james-opens-investigation-parcare-over-covid-19-vaccine>.

***Attorney General James Issues Alert to Protect New Yorkers from Coronavirus Vaccine Scams***—December 28, 2020—New York AG James issued an alert to warn New Yorkers about potential scams offering early access to a COVID-19 vaccine. Throughout the pandemic, scammers have found ways to victimize the public, with the vaccine distribution process also being a method for fraud. The OAG recommended the following tips to avoid vaccine-related scams: be wary of calls/emails with offers of a vaccine; refrain from giving out social security number, personal credit card, or bank account information; and be wary of emails/texts about being on a COVID-19 vaccine list. <https://ag.ny.gov/press-release/2020/attorney-general-james-issues-alert-protect-new-yorkers-coronavirus-vaccine-scams>.

***AG James Issues Statement on New York Vaccine Equity Task Force Appointment***—December 22, 2020—AG James was appointed to the New York Vaccine Equity Task Force in response to the COVID-19 pandemic. She released the following statement on her appointment: “It is vital that New York does everything in its power to eliminate barriers between the vaccine and marginalized communities, which are also the communities most devastated by the pandemic. Without equitable vaccine distribution, COVID-19 will remain a plight throughout our state, and will cost us more lives. It is my honor to serve as a co-chair on this task force and help ensure our most vulnerable communities get access to vaccines as quickly and as efficiently as possible.” <https://ag.ny.gov/press-release/2020/ag-james-issues-statement-new-york-vaccine-equity-task-force-appointment>.

***Attorney General James Continues Fight to Safeguard Women’s Access to Reproductive Health Care***—December 22, 2020—AG James, as part of a coalition of 20 attorneys general, filed an amicus brief in *Memphis Center for Reproductive Health, et al. v. Herbert Slatery, et al.*, contesting the constitutionality of two abortion bans enacted in the State of Tennessee. The amicus brief urges the court to

affirm a lower court injunction that prevents the enforcement of a Tennessee law that would create barriers to safe, legal abortions, and would disproportionately impact Black, minority, and low-income women. The coalition maintains that the laws place unconstitutional restrictions on a woman's right to choose. <https://ag.ny.gov/press-release/2020/attorney-general-james-continues-fight-safeguard-womens-access-reproductive>.

***AG James Secures \$6 Million Over False Medicaid Billing Scheme at an Inpatient Drug Treatment Center***—December 21, 2020—AG James announced a settlement with A.R.E.B.A.-CASRIEL, Inc. d/b/a Addiction Care Interventions Chemical Dependency Treatment (ACI) and its majority owner, Steven Yohay, regarding multiple schemes to defraud the New York State Medicaid Program. Under the settlement, ACI and Yohay admitted that they failed to respond to reports of wrongdoing, and that ACI engaged in a number of illegal schemes, including that its employees bribed people experiencing homelessness to receive inpatient treatment at ACI. To resolve these allegations, ACI agreed to reimburse \$3 million to the Medicaid Program. Additionally, Yohay personally agreed to reimburse the Medicaid Program another \$3 million, and is excluded from participation in any government-funded health care programs for 15 years. All current owners of ACI, including Yohay's brother, also agreed to divest themselves of their ownership interests in the corporation. <https://ag.ny.gov/press-release/2020/ag-james-secures-6-million-over-false-medicaid-billing-scheme-inpatient-drug>.

***Attorney General James' Statement on Opioid Filings Detailing How Sackler Family Personally Ran Purdue Pharma and Directed Billions in Profits Into Personal Bank Accounts and Trusts***—December 19, 2020—AG James issued a statement following updated filings by the official committee of unsecured creditors in the lawsuits against Purdue Pharma and the Sackler family. The updated filings revealed that the Sacklers personally directed and oversaw the illegal transfer of billions of dollars out of Purdue bank accounts and into personal accounts and trusts of Sackler family members. The filings also revealed that the Sackler family had direct control over all material decisions made by Purdue. <https://ag.ny.gov/press-release/2020/attorney-general-james-statement-opioid-filings-detailing-how-sackler-family>.

***Attorney General James and the Hispanic Federation Issue Joint Statement on the Appointment of California Attorney General Xavier Becerra to U.S. Secretary of Health and Human Services***—December 8, 2020—AG James and Frankie Miranda, president and Chief Executive Officer of the Hispanic Federation released a statement congratulating California Attorney General Xavier Becerra on his appointment to U.S. Secretary for Health and Human Services. The statement emphasized that Attorney General Becerra has a track record of fighting for underserved communities, expanding access to quality, affordable health care, and for helping drive the

passage of the Affordable Care Act. <https://ag.ny.gov/press-release/2020/attorney-general-james-and-hispanic-federation-issue-joint-statement-appointment>.

***Attorney General James Calls on Congress to Ensure Equitable Access to COVID-19 Vaccine***—December 4, 2020—AG James led a coalition of 13 state attorneys general to urge Congress to allocate funding and codify coverage protections to guarantee that all people living in the United States are able to obtain a COVID-19 vaccine at no cost. The joint letter recommends that Congress codify the recent Centers for Medicare and Medicaid Services (CMS) Interim Final Rule allowing any vaccine authorized by the Food and Drug Administration (FDA) to be covered at no cost to Medicare beneficiaries; and that the Provider Relief Fund, which provides uninsured individuals with access to the vaccine, must also cover co-pay or out-of-pocket fees. The joint letter also urged Congress to provide States with additional financial assistance to supplement the Family First Coronavirus Response Act by ensuring that payment rates to providers are sufficient to allow Medicaid recipients to access the vaccine at no cost. <https://ag.ny.gov/press-release/2020/attorney-general-james-calls-congress-ensure-equitable-access-covid-19-vaccine>.

***Attorney General James Ready to Sue Trump Administration if New York Doesn't Receive COVID-19 Vaccine with Rest of U.S.***—November 13, 2020—AG James released a statement after former president Donald J. Trump announced that a COVID-19 vaccine then in development would not be sent to New York once complete. AG James stated that if dissemination of the vaccine took place during the Trump Administration and New York were to be denied access, the OAG would file suit against the Trump Administration. <https://ag.ny.gov/press-release/2020/attorney-general-james-ready-sue-trump-administration-if-new-york-doesnt-receive>.

***Attorney General James' Statement on ACA Supreme Court Oral Arguments***—November 10, 2020—AG James and a coalition of 20 States and the District of Columbia defended the Patient Protection and Affordable Care Act (ACA) in the United States Supreme Court in the case *California v. Texas*. The coalition defended the entirety of the ACA—including coverage of preexisting conditions, public health investments, and Medicaid expansion, among others—against the Trump Administration and a Texas-led State coalition seeking to dismantle the health care law. The Trump Administration argued that all provisions of the ACA should be held invalid, since the individual mandate was held unconstitutional. While the U.S. Court of Appeals for the Fifth Circuit held the individual mandate to be unconstitutional, it remanded the case back to the U.S. District Court for the Northern District of Texas to determine the validity of the ACA's remaining provisions. In January 2020, AG James and the coalition petitioned the Supreme Court for expedited review. The Supreme Court granted review of the case in March for the upcoming term. <https://ag.ny.gov/press-release/2020/>

attorney-general-james-statement-aca-supreme-court-oral-arguments.

***Attorney General James Defends ACA on Eve of Supreme Court Oral Arguments***—November 9, 2020—AG James continued her strong defense of the ACA ahead of the oral arguments scheduled for November 10, 2020 before the United States Supreme Court in *California v. Texas*. AG James released a statement opining that the case is even more dangerous in light of the COVID-19 pandemic, and asserting that invalidating the entirety or certain provisions of the ACA could cause millions of Americans to lose coverage amid the COVID-19 pandemic. <https://ag.ny.gov/press-release/2020/attorney-general-james-defends-aca-eve-supreme-court-oral-arguments>.

***Court Directs Jury Selection to Begin in Opioid Trial in January***—October 28, 2020—Suffolk County State Supreme Court directed jury selection to begin in the trial against multiple opioid manufacturers and distributors in January of 2021. Justice Jerry Garguilo directed jury selection to begin in January of 2021, and estimated that the trial would begin in February or March of 2021. The trial was originally set to begin on March 20, 2020, but was delayed by the court due to the COVID-19 pandemic. The trial is the next step in a lawsuit filed by AG James and coalition of attorneys general against multiple opioid manufacturers and distributors. The defendants in the suit include Purdue Pharma, its affiliates, and the Sackler family, Janssen Pharmaceuticals and its affiliates, Mallinckrodt LLC and its affiliates, Endo Health Solutions and its affiliates, Teva Pharmaceuticals USA, Inc. and its affiliates, and Allergan Finance, LLC and its affiliates. The distributors named in the complaint include McKesson Corporation, Cardinal Health Inc., Amerisource Bergen Drug Corporation, and Rochester Drug Cooperative Inc. The upcoming trial will cover AG James' lawsuits against all manufacturers and distributors other than Purdue Pharma, the Sackler family, and Mallinckrodt, as the case against these three defendants is moving separately in the U.S. Bankruptcy Court. <https://ag.ny.gov/press-release/2020/court-directs-jury-selection-begin-opioid-trial-january>.

***Attorney General James' Statement in Response to Deal Between U.S. DOJ and Purdue Pharma/Sackler Family***—October 21, 2020—AG James responded to a deal announced between the U.S. Department of Justice and opioid manufacturer Purdue Pharma and its owner, the Sackler family. AG James strongly opposed the deal and asserted that it does not account for the deaths and millions of addictions allegedly caused by Purdue Pharma and the Sackler family. AG James further asserted that her office would continue to litigate the case through the courts to secure recovery for the alleged victims and to limit future opioid addictions. <https://ag.ny.gov/press-release/2020/attorney-general-james-statement-response-deal-between-us-doj-and-purdue>.

***Attorney General James Continues Fight to Stop Health Care Discrimination Promulgated by Trump Ad-***

***ministration***—October 21, 2020—AG James led a coalition of 22 attorneys general opposing the Trump Administration's "Refusal-of-Care" rule introduced in May 2019. The rule allows health care providers to refuse to provide health coverage and medical services to individuals on the basis of health care provider's own religious beliefs or moral convictions. AG James asserted that the rule allows health care providers to openly discriminate among patients, and that the rule would disproportionately impact women and members of the lesbian, gay, bisexual, transgender and queer (LGBTQ+) community. Every federal court that has considered the rule has agreed that it is not authorized by law and has vacated the rule in full, including the U.S. District Court for the Northern District of California and the U.S. District Court for the Eastern District of Washington. The Trump Administration appealed to the U.S. Court of Appeals for the Ninth Circuit in response to the outcomes in California and Washington. AG James and the coalition filed an amicus brief in support of California and Washington in that appeal. The coalition explains that the rule threatens to harm patients in disrupting their access to medically necessary care, and also places billions in critical federal health care funding that Congress has appropriated to the States at risk. In addition, AG James led her own lawsuit against the Trump Administration's "Refusal-of-Care" rule in the U.S. District Court for the Southern District of New York in May of 2019. AG James won that case in federal court, and the Trump Administration appealed the matter in the U.S. Court of Appeals for the Second Circuit. <https://ag.ny.gov/press-release/2020/attorney-general-james-continues-fight-stop-health-care-discrimination>.

***Attorney General James Charges Bronx Clinic Owner With Stealing More Than \$4 Million From New York Taxpayers***—October 09, 2020—Charges were announced against a Bronx woman and her health care clinic for defrauding the New York State Medicaid Program. It is alleged that the defendants pocketed more than \$4 million by submitting false claims to the Medicaid Program and MetroPlus. The scheme also allegedly involved tricking individuals into divulging personal information under the false pretense of applying for affordable housing and using that information to submit false claims. <https://ag.ny.gov/press-release/2020/attorney-general-james-charges-bronx-clinic-owner-stealing-more-4-million-new>.

***Attorney General James Leads Coalition Seeking Supreme Court Review of Trump Administration's Title X Family Planning Rule***—October 06, 2020—AG James and a coalition of 22 attorneys general from around the nation have filed a petition asking the U.S. Supreme Court to review a circuit court decision upholding the Trump Administration's Title X family planning rule, also known as the "gag rule." The gag rule places restrictions on referrals for abortions and counseling related to abortions for providers at clinics that receive Title X funds, which prevents providers from fully informing patients of the reproductive health services available to them. Another provision re-

quires such clinics to physically segregate abortion services and the provision of referrals for abortion from all Title X funded services. Due to the expense and difficulty meeting the requirement, many providers have been driven out of the program and could face a loss of business. <https://ag.ny.gov/press-release/2020/attorney-general-james-leads-coalition-seeking-supreme-court-review-trump>.

**Attorney General James Secures \$4 Million from Companies Involved in Alleged Fraudulent Physical Therapy Scheme**—October 02, 2020—Several physical therapy offices operated throughout New York City have come to an agreement with the OAG to pay \$4 million in order to resolve allegations that the owners and their companies falsely billed the Medicaid Program and other federal health care programs for physical therapy services, as well as for having had non-licensed individuals provide physical therapy services. The case was originally initiated by former employees and whistleblowers who will receive a portion of the settlement. <https://ag.ny.gov/press-release/2020/attorney-general-james-secures-4-million-companies-involved-alleged-fraudulent>.

**Attorney General James Helps Secure \$39.5 Million After Anthem's 2014 Data Breach**—September 30, 2020—The OAG has reached a \$39.5 million settlement with health insurance company Anthem, Inc., following a massive data breach that compromised the personal information of 78.8 million customers nationwide. Along with paying millions of dollars, Anthem will make a series of changes to its security protocols designed to strengthen practices going forward. <https://ag.ny.gov/press-release/2020/attorney-general-james-helps-secure-395-million-after-anthems-2014-data-breach>.

**Attorney General James Delivers \$22.7 Million in Busting Pharmaceutical Company for Its Kickback Scheme**—September 25, 2020—The OAG has reached a \$22.7 million settlement with a pharmaceutical company to resolve allegations of kickbacks. The pharmaceutical company, Novartis, allegedly paid kickbacks to health care providers in the form of cash, lavish meals, entertainment, and honoraria payments to induce them to prescribe various Novartis-brand medications. The company admitted to aspects of the scheme in the agreement, including excessive meal and alcohol spending, minimal medical discussions at events, and repeat attendance. The company also admitted that at least one sales representative organized fraudulent speaker programs by arranging for a restaurant to create fake receipts to make it appear that a dinner had taken place, and then used the budgeted funds to purchase gift cards that were distributed to high-prescribing doctors. Doctors were then also paid honoraria for supposedly “speaking” at these sham events. The case was originally initiated by former employees and whistleblowers who will receive a portion of the settlement. <https://ag.ny.gov/press-release/2020/attorney-general-james-delivers-227-million-busting-pharmaceutical-company-its>.

**Attorney General James Helps Recover \$60 Million from Company That Endangered Women's Health**—September 24, 2020—AG James and a coalition of 49 attorneys general have announced a multistate agreement that requires two companies to pay \$60 million for deceptive marketing of transvaginal surgical mesh devices that endangered the health of women across the nation. The companies allegedly violated state consumer protection laws by misrepresenting or failing to adequately disclose serious and life-altering risks of surgical mesh devices, such as chronic pain, scarring and shrinking of bodily tissue, painful sexual relations, and recurring infections, among other complications. The agreement will also require, among other things, the companies to provide patients with understandable descriptions of complications in marketing materials and disclose complications related to the use of mesh. <https://ag.ny.gov/press-release/2020/attorney-general-james-helps-recover-60-million-company-endangered-womens-health>.

## **New York State Office of the Medicaid Inspector General Update**

Compiled by Dena M. DeFazio

OMIG Assists in Investigation that Leads to Arrests of NYC Psychiatrist, Medical Assistant for Allegedly Selling Prescription Drugs for Cash—November 25, 2020—<https://omig.ny.gov/news/2020/omig-assists-investigation-leads-arrests-nyc-psychiatrist-medical-assistant-allegedly>.

UPDATE: Physical Therapist Who Participated in \$30 Million Health Care Fraud Scheme Sentenced in Federal Court—October 21, 2020—<https://omig.ny.gov/news/2020/update-physical-therapist-who-participated-30-million-health-care-fraud-scheme-sentenced>.

## **Endnotes**

1. Please note that these decisions are summarized after they are posted on the Department of Health's website, which is often many months after the date of the decision.
2. The editor wishes to thank Barclay Damon LLP intern Syeda Zahra, who assisted in the summaries of these press releases.

# In the Law Journals

By Cassandra DiNova

*50 Years Post-Controlled Substances Act: The War on Drugs Rages On With Opioids at the Forefront*, Roseann B. Termini and Rachel Malloy-Good, 46 Ohio N.U. L. Rev. 1 (2020).

*A Match in Antitrust Heaven? A Liberalistic Exploration of the Medical Match's Antitrust Exemption*, Melissa Mayeux, 13 Wash. U. Jurisprudence Rev. 121 (2020).

*A Path to Data-Driven Health Care Enforcement*, Jacob T. Elbergal, 2020 Utah L. Rev. 1169 (2020).

*Against Fiduciary Utopianism: The Regulation of Physician Conflicts of Interest and Standards of Care*, Sam F. Halabi, 11 UC Irvine L. Rev. 433 (Dec. 2020).

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*Bioethics—"Who Do They Think They Are?": Protecting Terminally Ill Patients Against Undue Influence by Insurers in States Where Medical Aid in Dying Is Legal*, Mary C. Deneen, 42 W. New Eng. L. Rev. 63 (2020).

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*COVID-19 and Preventing Harm to Vulnerable Children*, Jessica K. Heldman, Margaret A. Dalton, Robert C. Fellmeth, 57 San Diego L. Rev. 865 (Nov.-Dec. 2020).

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*Data of the Dead: A Proposal for Protecting Posthumous Data*, Kate C. Ashley, 62 Wm. & Mary L. Rev. 649 (Nov. 2020).

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*Decisions in the Dark: Why "Pregnancy Exclusion" Statutes Are Unconstitutional and Unethical*, Shea Flanagan, 114 Nw. U. L. Rev. 969 (2020).

*Designing Children: Tort Liability for Medical Providers in the Era of CRISPR/Cas-9 Genetic Editing*, Sarah Roa, 47 Mitchell Hamline L. Rev. 300 (Feb. 2021).

*Exposing the Middlemen in Rising Drug Costs: Modifying Safe Harbor Protections For Pharmacy Benefit Manager Rebates Under Federal Anti-Kickback Statutes*, Abigail Gore, 98 Or. L. Rev. 297 (2020).

*Laboratories of Exclusion: Medicaid, Federalism & Immigrants*, Medha D. Makhoul, 95 N.Y.U. L. Rev. 1680 (Dec. 2020).

*Medical Disputes and Conflicting Values: Is There a "Right To Die" Later?*, Janet L. Dolgin, 2020 B.Y.U. L. Rev. 95 (2020).

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*Physicians Beware! The Patients May Be Secretly Recording the Encounter*, Samuel D. Hodge, Jr., 23 Quinnipiac Health L.J. 229 (2020).

*Pretrial Dismissal in the Interest of Justice: A Response to COVID-19 and Protest Arrests*, Valena E. Beety, 11/16/2020 U. Chi. L. Rev. Online 44 (Nov. 2020).

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*Seize The Moment: The Opportunity to Realize the Human Right to Healthcare in the United States*, Fran Quigley, 17 Ind. Health L. Rev. 53 (2020).

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**Cassandra DiNova is an Associate Attorney of Rivkin Radler LLP, part of their Health Services Group.**

*So You Want To Start a Health Plan?: Federal Laws Supporting and Undermining the Creation of PSHPS*, Matthew D. Reed, 53 Ind. L. Rev. 399 (2020).

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*The Right to Conscience vs. The Right To Die: Physician-Assisted Suicide, Catholic Hospitals, and the Rising Threat to Institutional Free Exercise in Healthcare*, Zachary R. Carstens, 48 Pepp. L. Rev. 175 (Jan. 2021).

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# For Your Information

By Claudia O. Torrey

As I pen this brief column for the due date of March 8, my part of the country has spent the prior two weeks with weather challenges! One week of snow, ice, sleet, rolling power outages, and one day with a 15+ power outages; the next week/weekend was full of rain, thunderstorms, and some hail!! All things considered, I am grateful and hope your new year has so far been safe and healthy. I trust you find the following information interesting:

- With a nod to International Women’s Day (celebrated on March 8), I was invited to “view” a signing of a Memorandum of Understanding between the Director General of the World Health Organization (WHO), Dr. Tedros A. Ghebreyesus, and Dr. Roopa Dhatt, Executive Director of Women in Global Health, regarding gender equality and pay equity in health care. The overall theme of the event was Women Leadership in the Health and Care Workforce, and was held in English, Spanish, and French. Some of the impressive speakers included Professor Address Malata, Vice Chancellor of the Malawi University of Science and Technology; Ms. Anita Bhatia, Deputy Executive Director, United Nations Women (UN); and Ambassador Delphine O, Ambassador Secretary General, UN Women’s Global Forum.

- The week of March 7, 2021 was the one-year anniversary of the WHO’s designation of COVID-19 as a global pandemic.
- While the COVID-19 vaccines are a “welcome relief,” there is also technology known as CRISPR-Cas9 (CRISPR, pronounced crisper) that may prove enlightening.<sup>1</sup> CRISPR technology is a tool for editing genomes which alter DNA sequences that could include treating and preventing the spread of diseases, as well as correcting genetic defects.<sup>2</sup> There is also a relatively new book<sup>3</sup> on the subject by Tulane University professor Walter Isaacson (also an advisory partner at Perella Weinberg Partners, a New York City-based financial services firm).

## Endnotes

1. Aparna Vidyasagar, *What Is CRISPR?* (livescience.com, April 21, 2018).
2. *Supra.*
3. Walter Isaacson, *The Code Breaker: Jennifer Doudna, Gene Editing, and the Future of the Human Race* (2021).

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**Claudia O. Torrey is a Charter Member of the Health Law Section.**



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# Federal Health Care Program Exclusion Lists and the Employee Screening Process

William P. Keefer and Michael Borrello

## Introduction

Which termination or exclusion lists are health care providers required to check when hiring new employees or contractors? The United States Department of Health and Human Services Office of Inspector General (HHS-OIG) and the Centers for Medicare & Medicaid Services (CMS) each have lists. Like the vast majority of states, New York State has its own Medicaid Exclusion List, which is administered by the New York State Office of the Medicaid Inspector General (OMIG). This article is intended to provide some background on federal health care program exclusion lists suggesting a contractor/employee screening process for health care providers.

## OIG's Exclusion Authority and a Brief Legislative History of Exclusion From Federal Health Care Programs

The HHS-OIG was established to “identify and eliminate fraud, waste, and abuse” in HHS programs and to “promote efficiency and economy” in HHS operations.<sup>1</sup> The HHS Secretary has delegated authority to OIG to “exclude from participation in Medicare, Medicaid, and other federal health care programs<sup>2</sup> persons that have engaged in fraud or abuse and to impose civil money penalties (CMPs) for certain misconduct related to federal health care programs.”<sup>3</sup>

The 1977 Medicare-Medicaid Anti-Fraud and Abuse Amendments, codified at Section 1128 of the Social Security Act (“Act”), first provided for exclusions from Medicaid and Medicare of physicians and practitioners convicted of certain crimes.<sup>4</sup> Then, in 1981, the Civil Monetary Penalties (CMP) Law, codified at Section 1128A of the Act, imposed civil liability—including monetary penalties, assessments and exclusion from federal health care programs—for health care fraud and abuse.<sup>5</sup> Subsequent legislation further strengthened OIG’s sanction authority—introducing, for instance, mandatory and discretionary exclusions for certain misconduct,<sup>6</sup> and expanding the scope of exclusion beyond Medicare and Medicaid to all federal health care programs.<sup>7</sup>

Section 1128 of the Act mandates the exclusion of physicians and health care practitioners from federal health care programs for convictions relating to patient abuse, felony health care fraud, felony controlled substance and program-related crimes.<sup>8</sup> Permissive exclusions, whereby OIG *may* exclude physicians and health care practitioners from federal health care programs, include convictions

for misdemeanor fraud, obstruction of an investigation or audit, misdemeanor distribution of a controlled substance, exclusion from a state Medicaid program, and default on health and education loan or scholarship obligations, among other things.<sup>9</sup>

Submission of a claim for payment for services rendered by an excluded person to a federal health care program, or causing such a claim to be submitted, is subject to criminal prosecution and/or CMP liability of up to \$20,000, an assessment for up to three times the amount of the claim, and denial of future participation in federal health care programs.<sup>10</sup>

## The Effects of Exclusion

Federal health care program exclusion has wide-ranging implications for the various parties in the health care services chain. Most directly, no payment shall be made by a federal health care program for any item or service furnished by an excluded individual or entity.<sup>11</sup> The prohibition on payment applies regardless of the type, “whether from itemized claims, cost reports, fee schedules, capitated payments, a prospective payment system or other bundled payment, or other payment system.”<sup>12</sup> For instance, “no payment may be made to a hospital for the items or services furnished by an excluded nurse to federal health care program beneficiaries, even if the nurse’s services are not separately billed and are paid for as part of a Medicare diagnosis-related group payment received by the hospital.”<sup>13</sup> Such nurse would be in violation of his or her exclusion for causing claims to be submitted to federal health care programs while he or she was excluded.<sup>14</sup>

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**William P. Keefer is the leader of Phillips Lytle LLP’s health law team and practices in the firm’s Buffalo office. Keefer is also the Co-chair of the New York State Bar Association Health Law Section’s Payment, Enforcement and Compliance Committee, and was formerly the chair of the Bar Association of Erie County Health Law Committee.**

**Michael Borrello is a corporate and health care regulatory attorney and who serves as in-house counsel at a Buffalo-based tech startup.**

Additionally, no payment shall be made for any item or service furnished *at the direction or on the prescription* of an individual who is excluded when the person furnishing such item or service knew, or had reason to know, of the exclusion.<sup>15</sup> Thus, to avoid liability, providers that furnish items and services on the basis of orders or prescriptions, such as laboratories, imaging centers, durable medical equipment suppliers and pharmacies, “should ensure, at the point of service, that the ordering or prescribing physician is not excluded.”<sup>16</sup>

Further, under Section 1128A of the Act, providers that employ or contract with excluded persons to provide items or services payable by federal health care programs may be subject to CMPs.<sup>17</sup>

If a health care provider arranges or contracts (by employment or otherwise) with a person that the provider knows or should know is excluded . . . the provider may be subject to CMP liability if the excluded person provides services payable, directly or indirectly, by a Federal health care program.<sup>18</sup>

Notwithstanding this strict prohibition, a provider may employ or contract with an excluded person in limited situations.<sup>19</sup> For example, if federal health care programs do not pay, directly or indirectly, for the items or services being provided by the excluded individual, then a provider that participates in federal health care programs may employ or contract with an excluded person to provide such items or services.<sup>20</sup>

Thus, because providers may be subject to liability for partnering with excluded individuals, all persons that provide items or services payable under federal health care programs should be screened by providers, including employees, contractors, subcontractors and the employees of contractors.<sup>21</sup> “For example, OIG recommends that providers screen nurses provided by staffing agencies, physician groups that contract with hospitals to provide emergency room coverage, and billing or coding contractors.”<sup>22</sup>

### **OIG’s List of Excluded Individuals/Entities**

In order to avoid potential liability, OIG urges health care providers and entities to check the OIG List of Excluded Individuals/Entities (LEIE) prior to hiring or contracting with individuals or entities.<sup>23</sup> The LEIE includes:

1. The name of the excluded person at the time of the exclusion;
2. The person’s provider type;
3. The authority under which the person was excluded;

4. The state where the excluded individual resided at the time of exclusion, or the state where the entity was doing business; and
5. National Provider Identifier (NPI).<sup>24</sup>

The LEIE is updated monthly, and OIG recommends that providers screen individuals prior to hiring or contracting, and then regularly afterwards, to ensure compliance.<sup>25</sup>

OIG recommends that providers use the LEIE as the primary source of information about OIG exclusions because it is maintained by OIG; updated monthly; and provides important details, including the statutory basis for the exclusion action, the person’s occupation at the time of exclusion, the person’s date of birth and address information.<sup>26</sup> Also, OIG staff are able to provide support with respect to the LEIE, such as responding to questions and verifying information regarding persons identified on the LEIE.<sup>27</sup>

It is also important for providers to consult the lists published by the state Medicaid programs to which the providers submit claims for items or services that are paid for by that state’s Medicaid program, in addition to the LEIE. The various state agencies administering or supervising the administration of state health care programs (“State Agencies”) may prosecute and sanction providers on their own initiative when state law authorizes them to do so.<sup>28</sup> They may also extend exclusions beyond the time periods imposed by OIG.<sup>29</sup> The regulations governing state-initiated exclusions from Medicaid are clear that “the provisions of these regulations are minimum requirements.<sup>30</sup> Even when OIG exercises its permissive exclusion authority based on a State Medicaid program exclusion, there may be some delay between the effective date of the state Medicaid program exclusion and an exclusion by the OIG, and the posting of the exclusion to the LEIE.<sup>31</sup>

### **State Agency Termination Reporting Under the Patient Protection and Affordable Care Act**

Section 6501 of the Patient Protection and Affordable Care Act (ACA) amended Section 1902(a)(39) of the Act to require *State Agencies* to terminate the Medicaid participation of any individual or entity that is terminated under Medicare or any other state plan, where such termination is included by the HHS Secretary in a database or similar system.<sup>32</sup> Terminations have the same effect as an exclusion, as no federal health care program payments can be paid for services provided by a terminated individual.<sup>33</sup>

The ACA requires that CMS establish a process for sharing information about terminated providers.<sup>34</sup> To meet this requirement, CMS developed a web-based application called the Medicaid and Children’s Health Insurance Program State Information Sharing System (MCSIS). States were intended to download information regarding terminated providers in other states and to upload infor-



mation regarding their own terminations.<sup>35</sup> State Agencies were encouraged by CMS to report provider terminations to populate MCSIS, but were not mandated.<sup>36</sup>

In 2012, CMS issued guidance emphasizing that it is only interested in being notified of “for cause” terminations, which constitute instances when “a State Medicaid program, [Children’s Health Insurance Program (CHIP)], or the Medicare program has taken action to revoke a Medicaid or CHIP provider’s or Medicare provider or supplier’s billing privileges and the provider has exhausted all applicable appeal rights or the timeline for appeal has expired.”<sup>37</sup> As a rule, “for cause” does not include “any voluntary action taken by the provider to end its participation in the Medicaid program, except where that ‘voluntary’ action is taken to avoid sanction.”<sup>38</sup>

According to CMS, examples of “for cause” terminations include:

1. Providers that are terminated by State Medicaid Agencies because they have engaged in fraudulent conduct;
2. Providers that are terminated by State Medicaid Agencies due to abuse of billing privileges, e.g., billing for services not rendered or for medically unnecessary services;
3. Providers that are terminated by State Medicaid Agencies due to misuse of their billing number;

4. Providers that are terminated by State Medicaid Agencies due to falsification of information on enrollment application or information submitted to maintain enrollment; and
5. Providers that are terminated by State Medicaid Agencies due to continued billing after the suspension or revocation of the provider’s medical license.<sup>39</sup>

Despite CMS’s attempts to maintain a database of Medicaid terminations to help State Agencies comply with Section 1902(a)(39) of the Act, MCSIS was rife with problems, and OIG was critical of CMS’s efforts. In March 2014, OIG published CMS’s *Process for Sharing Information About Terminated Providers Needs Improvement*, which found that MCSIS had no records for 27 State Agencies; only about one-third of the 6,439 records in MCSIS related to providers terminated “for cause”; over half of MCSIS records did not contain NPIs; and only one-third of MCSIS records identified provider types.<sup>40</sup> OIG recommended that CMS “(1) require each State Medicaid agency to report all terminated providers, (2) ensure that the shared information contains only records that meet CMS’s criteria for inclusion, and (3) take action to improve the completeness of records shared through the process.”<sup>41</sup>

CMS took the advice and “implemented procedures intended to improve the completeness of the records, such as requiring States to submit a copy of the Medicaid termination letter issued to the provider as well as

information such as the provider's NPI or SSN."<sup>42</sup> It also began reviewing each termination to assure that it meets CMS criteria for inclusion in the Termination Notification database.<sup>43</sup>

Still, in August 2015, OIG released a report entitled *Providers Terminated From One State Medicaid Program Continued Participating in Other States*, which found that, among other things, 12% of providers who were terminated for cause from State Medicaid programs in 2011 continued participating in Medicaid in other states.<sup>44</sup> OIG recommended that CMS "(1) work with States to develop uniform terminology to clearly denote terminations for cause, (2) require that State Medicaid programs enroll all providers participating in Medicaid managed care, and (3) furnish guidance to State agencies that termination is not contingent on the provider's active licensure status."<sup>45</sup>

In response to the draft OIG report, *CMS System for Sharing Information About Terminated Providers Needs Improvement*, CMS responded that it had phased out MCSIS and transitioned to the One Program Integrity (OnePI) portal on November 25, 2013.<sup>46</sup> Still in use today,<sup>47</sup> OnePI allows for state-to-state information on terminated providers to be securely shared by CMS, state Medicaid, and CHIP staff.<sup>48</sup> OnePI allows State Agencies to view and download Medicare revocations, previous MCSIS data, and state Medicaid terminations.<sup>49</sup>

## Conclusion

When hiring employees or contractors to provide services that are payable by a federal health care program, New York health care providers should screen employees and contractors using OIG's LEIE database, the Medicaid Exclusion List (MEL) administered by OMIG, and the lists published by any other state Medicaid programs to which provider submits claims. Section 1902(a)(39) of the Act requires State Agencies, not providers, to terminate the participation of any individual or entity that is terminated under Medicare or any other state plan, where such termination is included by the HHS Secretary in a database or similar system. Thus, OMIG bears the responsibility for utilizing available CMS resources, such as OnePI, to populate the MEL with individuals and entities that have been excluded under other states' plans. Reviewing other states' databases may result in over-exclusion, as other states may report terminations or exclusions beyond the scope of what is required under New York State or federal law.

## Endnotes

1. OIG, Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs, 1 (May 8, 2013), <https://oig.hhs.gov/exclusions/files/sab-05092013.pdf>.
2. See OIG, *supra* note 1, at 2, n.1 ("A Federal health care program is defined as any plan or program that provides health benefits, whether directly, through insurance, or otherwise, and that is funded directly, in whole or in part, by the U.S. Government or a State health care program (except for the Federal Employees Health

Benefits Program) (section 1128B(f) of the Social Security Act (the Act)). Among the most significant Federal health care programs are Medicare, Medicaid, TRICARE, and the veterans' programs.").

3. OIG, *supra* note 1, at 1.
4. OIG, *supra* note 1, at 4; 42 U.S.C. § 1320a-7.
5. OIG, *supra* note 1, at 4; 42 U.S.C. § 1320a-7a.
6. See, e.g., Medicare and Medicaid Patient Program Protection Act of 1987, Pub. L. No. 100-93, 101 Stat. 680; Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066; Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, 124 Stat. 119, as amended by the Health Care and Education Reconciliation Act of 2010 (ACA), Pub. L. No. 111-152, 124 Stat. 1029; see also OIG, *supra* note 1, at 5.
7. See, e.g., Health Insurance Portability and Accountability Act (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936 (1996); Balanced Budget Act (BBA) of 1997, Pub. L. No. 105-33, 111 Stat. 251; see also OIG, *supra* note 1, at 5.
8. 42 U.S.C. § 1320a-7(a).
9. 42 U.S.C. § 1320a-7(b); see, e.g., OIG, Criteria for Implementing Section 1128(b)(7) Exclusion Authority (Apr. 18, 2016), <https://oig.hhs.gov/exclusions/files/1128b7exclusion-criteria.pdf>; 42 C.F.R. § 1001.601.
10. OIG, *supra* note 1, at 9.
11. 42 C.F.R. § 1001.1901(b)(1)(i).
12. OIG, *supra* note 1, at 6.
13. *Id.*
14. *Id.*
15. 42 C.F.R. § 1001.1901(b)(1)(ii).
16. OIG, *supra* note 1, at 8.
17. 42 U.S.C. § 1320a-7a(a)(6).

(Any person . . . that . . . arranges or contracts (by employment or otherwise) with an individual or entity that the person knows or should know is excluded from participation in a Federal health care program (as defined in section 1320a-7b(f) of this title), for the provision of items or services for which payment may be made under such a program . . . shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than \$20,000 for each item or service[.]).

18. OIG, *supra* note 1, at 11.
19. OIG, *supra* note 1, at 12.
20. *Id.*
21. OIG, *supra* note 1, at 11:

(A provider could be subject to CMP liability if an excluded person participates in any way in the furnishing of items or services that are payable by a Federal health care program. CMP liability would apply to the furnishing of all of the categories of items or services that are violations of an OIG exclusion, including direct patient care, indirect patient care, administrative and management services, and items or services furnished at the medical direction or on the prescription of an excluded person when the person furnishing the services either knows or should know of the exclusion. CMP liability could result if the provider's claim to the Federal health care program includes any items or services furnished by an excluded person, even if the excluded person does not receive payments from the provider for his or her services (e.g., a non-employed excluded physician who is a member of a hospital's medical staff or an excluded health care professional who works at a hospital or nursing home as a volunteer). An excluded person may not provide services that are payable by Federal health care programs, regardless of whether the person is an employee, a contractor, or a volunteer or has any other relationship with the provider.)

See OIG, Exclusions Program, <https://oig.hhs.gov/exclusions/index.asp> (last visited Feb. 22, 2021) (“Anyone who hires an individual or entity on the LEIE may be subject to civil monetary penalties (CMP). To avoid CMP liability, health care entities should routinely check the list to ensure that new hires and current employees are not on it”); OIG, *supra* note 1, at 15-16.

22. OIG, *supra* note 1, at 16.
23. OIG, The Effect of Exclusion From Participation in Federal Health Care Programs, Special Advisory Bulletin (Sept. 1999), [https://oig.hhs.gov/exclusions/effects\\_of\\_exclusion.asp](https://oig.hhs.gov/exclusions/effects_of_exclusion.asp) (last visited Feb. 25, 2021).
24. See OIG, LEIE Downloadable Databases, [https://oig.hhs.gov/exclusions/exclusions\\_list.asp](https://oig.hhs.gov/exclusions/exclusions_list.asp) (last visited Feb. 22, 2021).
25. OIG, *supra* note 1, at 16.
26. OIG, *supra* note 1, at 17.
27. *Id.*
28. Health Care Programs: Fraud and Abuse; Amendments to OIG Exclusion and CMP Authorities Resulting From Public Law 100-93, 57 Fed. Reg. 3298, 3322 (Jan. 29, 1992).
29. Health Care Programs: Fraud and Abuse; Amendments to OIG Exclusion and CMP Authorities Resulting From Public Law 100-93, 57 Fed. Reg. 3298, 3322 (Jan. 29, 1992); *see, e.g.*, 18 N.Y.C.R.R. § 515.7:  
(Upon receiving notice that a person has been found to have violated a State or Federal statute or regulation pursuant to a final decision . . . where the violation resulting in the final decision or determination would constitute an act described as professional misconduct or unprofessional conduct by the rules or regulations of the State Commissioner of Education or the State Board of Regents . . . the department may immediately sanction the person and any affiliate).
30. 42 C.F.R. § 1002.5; *see also* 42 C.F.R. § 455.452 (“Nothing in this subpart must restrict the State Medicaid agency from establishing provider screening methods in addition to or more stringent than those required by this subpart”).
31. Section 1128(b)(5) Act; 42 C.F.R. § 1001.601.
32. CMS, Affordable Care Act Program Integrity Provisions - Guidance to States -- Section 6501 - Termination of Provider Participation under Medicaid if Terminated under Medicare or other State Plan, CPI-B 12-02 (Jan. 20, 2012), at 1-2, <https://www.medicaid.gov/federal-policy-guidance/downloads/cib-01-20-12.pdf>. (alternative cite: ¶ 350,339 PPACA GUIDANCE TO STATES SECTION 6501-TERMINATION OF PROVIDER PARTICIPATION UNDER MEDICAID IF TERMINATED UNDER MEDICARE OR OTHER STATE PLAN, Healthcare Compl. Rep. P 350339); 42 U.S.C. § 1396a(a)(39), (§ 1902(a)(39) of the Social Security Act); *see also* 18 N.Y.C.R.R. § 515.8.
33. Ctrs. for Medicare & Medicaid Servs., Medicaid Program Integrity Education Podcast: Exclusions and Terminations Part 2 Transcript (Sept. 2015), [https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/podcast-Exclusions-and-Terminations-Part-2-transcript-\[September-2015\].pdf](https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/podcast-Exclusions-and-Terminations-Part-2-transcript-[September-2015].pdf) (citing 42 U.S.C. § 1396a(a)(39)); *see also* CMS, Frequently Asked Questions Section 6501 of the Affordable Care Act (May 2011), <https://downloads.cms.gov/cmsgov/archived-downloads/CMCSBulletins/downloads/6501-Term.pdf>:  
(For purposes of section 6501, a ‘termination’ occurs when the State terminates the participation of a Medicaid or CHIP provider from the program or the Medicare program has revoked a Medicare provider or supplier’s billing privileges, and the provider has exhausted its appeal rights or the timeline for appeal has expired. Generally, ‘exclusion’ from participation in a federal health care program, including Medicare, Medicaid, and CHIP is a penalty imposed on providers and suppliers by the Department’s Office of Inspector General (HHS-OIG). Individuals and entities may be excluded from participating in federal health care programs for misconduct ranging from fraud convictions to patient abuse to defaulting on health education loans. We recognize, however, that certain States give the same meaning to the terms ‘exclusion’ and ‘termination’ and these actions; therefore, ultimately result in the provider’s involuntary departure from the Medicaid program or CHIP).
34. OIG, CMS’s Process for Sharing Information About Terminated Providers Needs Improvement, OEI-06-12-00031, at 2 (Mar. 2014).
35. CMS, *supra* note 32, at 3.
36. OIG, Providers Terminated From One State Medicaid Program Continued Participating in Other States, Report No. OEI-06-12-00030, 8 (Aug. 2015), <https://oig.hhs.gov/oei/reports/oei-06-12-00030.pdf> (“Most of the available data sources are designed for purposes other than identifying providers terminated for cause, and therefore do not attempt to identify all such providers. Although the CMS Termination Notification database is designed for this purpose, States’ participation is encouraged, rather than required.”); *id.* at 3 (“In March 2014, OIG recommended that CMS require State Medicaid agencies to report all terminations for cause. We reiterate this prior recommendation as we found the lack of a comprehensive data source of providers terminated for cause creates a challenge for State Medicaid agencies.”).
37. CMS, *supra* note 32, at 1-2.
38. CMS, *supra* note 32, at 2.
39. CMS, *supra* note 32, at 2-3.
40. OIG, *supra* note 34, at 2.
41. *Id.*
42. OIG, Providers Terminated From One State Medicaid Program Continued Participating in Other States, OEI-06-12-00030, at 4 (Aug. 2015).
43. OIG, *supra* note 42, at 4.
44. OIG, *supra* note 42.
45. OIG, *supra* note 42, at 3.
46. OIG, *supra* note 34, at app. B.
47. See U.S. Dep’t of Health & Human Servs., Medicare Program Integrity Manual Chapter 2—Data Analysis, Rev. 10365, at 9 (Oct. 2020).
48. OIG, *supra* note 34, at app. B.
49. *Id.*

# Exclusion Authorities

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Office of the Inspector General

Available at <https://oig.hhs.gov/exclusions/authorities.asp>

Scope		
<b>Social Security Act</b>	<b>42 USC §</b>	<b>Amendment</b>
1128	1320a-7	Scope of exclusions imposed by OIG expanded from Medicare and State health care programs to all Federal health care programs, as defined in section 1128B(f)(1).

## Mandatory Exclusions

<b>Social Security Act</b>	<b>42 USC §</b>	<b>Amendment</b>
1128(a)(1)	1320a-7(a)(1)	Conviction of program-related crimes. Minimum Period: 5 years
1128(a)(2)	1320a-7(a)(2)	Conviction relating to patient abuse or neglect. Minimum Period: 5 years
1128(a)(3)	1320a-7(a)(3)	Felony conviction relating to health care fraud. Minimum Period: 5 years
1128(a)(4)	1320a-7(a)(4)	Felony conviction relating to controlled substance. Minimum Period: 5 years
1128(c)(3)(G)(i)	1320a-7(c)(3)(G)(i)	Conviction of second mandatory exclusion offense. Minimum Period: 10 years
1128(c)(3)(G)(ii)	1320a-7(c)(3)(G)(ii)	Conviction of third or more mandatory exclusion offenses. Permanent Exclusion

## Permissive Exclusions

<b>Social Security Act</b>	<b>42 USC §</b>	<b>Amendment</b>
1128(b)(1)(A)	1320a-7(b)(1)(A)	Misdemeanor conviction relating to health care fraud. Baseline Period: 3 years
1128(b)(1)(B)	1320a-7(b)(1)(B)	Conviction relating to fraud in non-health care programs. Baseline Period: 3 years
1128(b)(2)	1320a-7(b)(2)	Conviction relating to obstruction of an investigation or audit. Baseline Period: 3 years
1128(b)(3)	1320a-7(b)(3)	Misdemeanor conviction relating to controlled substance. Baseline Period: 3 years
1128(b)(4)	1320a-7(b)(4)	License revocation, suspension, or surrender. Minimum Period: Period imposed by the state licensing authority.
1128(b)(5)	1320a-7(b)(5)	Exclusion or suspension under federal or state health care program. Minimum Period: No less than the period imposed by federal or state health care program.

1128(b)(6)	1320a-7(b)(6)	Claims for excessive charges, unnecessary services or services which fail to meet professionally recognized standards of health care, or failure of an HMO to furnish medically necessary services. Minimum Period: 1 year
1128(b)(7)	1320a-7(b)(7)	Fraud, kickbacks, and other prohibited activities. Minimum Period: None
1128(b)(8)	1320a-7(b)(8)	Entities controlled by a sanctioned individual. Minimum Period: Same as length of individual's exclusion.
1128(b)(8)(A)	1320a-7(b)(8)(A)	Entities controlled by a family or household member of an excluded individual and where there has been a transfer of ownership/control. Minimum Period: Same as length of individual's exclusion.
1128(b)(9), (10), and (11)	1320a-7(b)(9), (10), and (11)	Failure to disclose required information, supply requested information on subcontractors and suppliers; or supply payment information. Minimum Period: None
1128(b)(12)	1320a-7(b)(12)	Failure to grant immediate access. Minimum Period: None
1128(b)(13)	1320a-7(b)(13)	Failure to take corrective action. Minimum Period: None
1128(b)(14)	1320a-7(b)(14)	Default on health education loan or scholarship obligations. Minimum Period: Until default or obligation has been resolved.
1128(b)(15)	1320a-7(b)(15)	Individuals controlling a sanctioned entity. Minimum Period: Same as length of entity's exclusion.
1128(b)(16)	1320a-7(b)(16)	Making false statement or misrepresentations of material fact. Minimum period: None.
1156	1320c-5	Failure to meet statutory obligations of practitioners and providers to provide medically necessary services meeting professionally recognized standards of health care (Quality Improvement Organization (QIO) findings). Minimum Period: 1 year

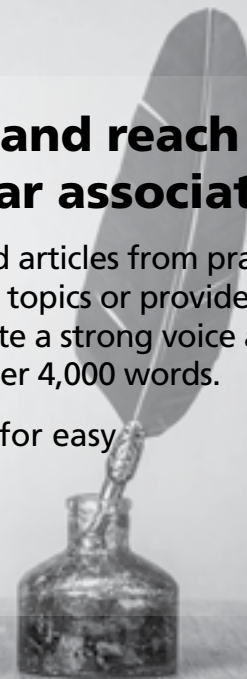
**Note:** except those imposed under section 1128(b)(7) (42 USC 1320a-7b(b)(7)), and those imposed on rural physicians under section 1156 (42 USC 1320C-5), all exclusions are effective prior to a hearing.

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# How Low Can You Go?: COVID-19 Crisis Tests Legal Parameters of Medicaid Reimbursement

By Linda Clark and Mary Connolly

Even before COVID-19, many health care providers were faced with unworkable reimbursement levels and rate-setting methods, leaving them too often in highly precarious, below-cost reimbursement positions. The pandemic and New York State's massive looming deficit has only served to punctuate the severity of the situation, setting the stage for a legal confrontation regarding the scope and nature of the state's fundamental obligation to provide quality care to those entitled to Medicaid benefits.

Prior to COVID-19, provider challenges to deep cuts in Medicaid funding were underway. Several types of providers filed challenges against the state based on a common theory: that the state's below-cost Medicaid reimbursement methodologies were both untenable and in violation of law. In those circumstances, courts generally did not hesitate to intervene and grant injunctive relief on substantive and procedural grounds where a reimbursement rate was inadequate, arbitrary, capricious, or in violation of state procedural requirements under the New York State Administrative Procedures Act (SAPA).

This article will explore the evolution of what constitutes adequate Medicaid reimbursement prior to and throughout the COVID-19 pandemic, and how the current legal landscape will impact future questions of adequate reimbursement in the Medicaid program. For many providers—and particularly those serving the developmentally disabled—the pandemic has compounded existing reimbursement issues, while also presenting new challenges to sustainable reimbursement levels.

## New York State's Medicaid Program

In New York State, the Department of Health ("the Department") is the single state agency charged with supervising the administration of the Medicaid program.<sup>1</sup> Historically, the Department has retained broad authority to regulate the use of public health funds and, in particular, the financial assistance granted by the state in connection with the public health.<sup>2</sup> Under the Medicaid program, the Department also has the responsibility to ensure the provision of high-quality medical care throughout the state and, as the program's administrator, has the authority to protect the quality and value of services rendered by providers in that program.<sup>3</sup>

In furtherance of that authority, the Department routinely promulgates regulations setting reimbursement rates for government-funded care and services.<sup>4</sup> As a result of that authority, the Department is often subjected

to challenges by providers regarding the adequacy of its assigned Medicaid reimbursement rate for a particular service. In recent years, those challenges have become more prevalent.

## Provider Challenges to Medicaid Reimbursement Pre-COVID-19

In late 2018, the Kings County Supreme Court enjoined implementation of a reduced Medicaid reimbursement rate on behalf of providers of incontinent supplies.<sup>5</sup> The providers claimed that the reduction would limit beneficiaries' access to the existing provider network for incontinence supplies insofar as the rates were reduced to the point where only preferred vendors would survive. Providers also claimed that the reduced reimbursement rate failed to take into account the overhead expenses incurred by community-based providers over the cost of the actual product, including costs associated with claims processing and delivery. In granting preliminary injunctive relief, the court determined that the potential loss of network providers due to inadequate reimbursement and the potential reduction in quality of service should recipients be forced to receive shipments from out-of-state suppliers rose to the level of irreparable harm absent an injunction.

Shortly thereafter, the Albany County Supreme Court concluded that a Department of Health managed care policy that changed the previous reimbursement rates of fiscal intermediaries for services provided to Medicaid fee-for-service members enrolled in the Consumer Directed Personal Assistance Program (CDPAP) was null and

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**Linda Clark is the Health Care Controversies Practice Area chair and a partner at Barclay Damon LLP. She advises health care providers, pharmaceutical companies, and pharmacies nationwide in resolving high-stakes disputes and government investigations. She represents health care professionals and entities in administrative proceedings, hearings, and appeals before various federal and state regulatory agencies.**

**Mary Connolly is an associate attorney at Barclay Damon LLP in its Albany office, concentrating her legal practice on representing health care providers in a variety of matters including health care-related litigation, arbitration, and audits, as well as regulatory, compliance, and transactional matters.**

void because the strict mandates of the New York SAPA were circumvented by the state.<sup>6</sup> In reaching this conclusion, the court determined that the managed care policy constituted a rule subject to notice, comment, and rule-making procedures because it applied to the reimbursement rate for *all* fiscal intermediaries.

In the same court, petitioner associations representing the interests of approximately 600 nursing homes across New York State and over 100 not-for-profit and for-profit nursing homes that receive Medicaid reimbursement obtained a preliminary injunction preventing the Department from implementing a new case mix adjustment methodology during the pendency of the proceeding.<sup>7</sup> Case mix adjustment is the method used by the Department to adjust nursing home Medicaid reimbursement rates.

The petitioners primarily argued that the new methodology contravened the Public Health Law and the Department's own regulations because the Department is required to make case mix adjustments in January and July of each calendar year, and the semiannual case mix adjustment must be based on data applicable to the prior case mix period or from the previous six months. Meanwhile, the Department, prior to July 1, 2019, based its semiannual case mix adjustment on patient acuity assessment data from a single-day "snapshot" of patient care. Holding that, among other things, the Department's change to an average calculation of patient acuity data was an unpro-mulgated rule, the court annulled the Department's case mix adjustments effective July 1, 2019.

### **OPWDD Voluntary Providers: The Canary in the Pandemic Cave**

Despite the favorable precedent laying the groundwork for reimbursement challenges, certain providers and programming have been forced to weather even heavier financial challenges since the COVID-19 pandemic started. Voluntary provider agencies certified by the Office for People With Developmental Disabilities (OPWDD) provide essential services to intellectually and developmentally disabled individuals. Individuals with developmental disabilities are afforded certain rights in that, under New York State law, the state has the statutory responsibility to provide comprehensive services including care, treatment habilitation, and rehabilitation of that vulnerable population.<sup>8</sup>

While rate setting and reimbursement calculation fall squarely within the purview of the Department with respect to long-term care and other services, the Department and OPWDD jointly administer Medicaid reimbursements for programs for persons with developmental disabilities. As such, the Department and OPWDD must work with voluntary agencies to not only deliver the necessary supports and services to this population but also are charged with creating a financial mechanism and reimbursement<sup>9</sup> scheme that adequately supports those services.

Before the COVID-19 pandemic, it was determined that voluntary provider agencies certified by OPWDD are entitled to be reimbursed their *actual* costs of providing high quality services.<sup>10</sup> Many of the services offered by these agencies are provided through New York's Home and Community Based Services (HCBS) waiver. The HCBS waiver is a program that enables adults and children with developmental disabilities to live in the community and remain at home as an alternative to a long term care facility.<sup>11</sup> The terms of the waiver, and any amendments to those terms, must be approved by the Centers for Medicare and Medicaid Services (CMS)—the federal agency that oversees the state's administration of the Medicaid program.<sup>12</sup> Upon approval of the waiver by CMS, the federal government will pay a portion of the state's Medicaid costs for approved waiver services.

The HCBS waiver provides for several services—including day habilitation, residential habilitation, and individual directed goods and services—that are critical to caring for individuals with developmental disabilities.<sup>13</sup> Services offered under the waiver enable individuals with developmental disabilities to gain social skills, a sense of community inclusion and relationship building, as well as opportunities to engage in self-advocacy and informed choice.<sup>14</sup> In New York, residential programming is offered through Individualized Residential Alternatives (IRAs) which are types of community residences or group homes that provide room, board, and individualized services.<sup>15</sup> Some IRAs provide 24-hour staff support and supervision and are classified as Supervised IRAs, while others called Supportive IRAs provide a lower level of care for residents who are able to safely live more independently.<sup>16</sup>

To qualify for services under the HCBS waiver program, an individual must have a diagnosis of a developmental disability; be enrolled or eligible for enrollment in Medicaid; choose to receive waiver services rather than services in an institutional setting; and reside in an appropriate living arrangement in which he or she can receive HCBS services in the community.<sup>17</sup>

While these services are necessary to the development of this vulnerable population, voluntary agencies have battled the state for adequate reimbursement since the start of COVID-19. In addition to below-cost reimbursement rates,<sup>18</sup> these agencies have been faced with withholds, outright funding cuts, and various programmatic and fiscal changes that contribute to large budgetary deficits. According to statewide coalitions, OPWDD faces nearly half a billion dollars in funding cuts and other withholdings amid the COVID-19 pandemic.<sup>19</sup>

A few months into the state's COVID-19 shutdown, a day habilitation program provider challenged the determination of the Department and OPWDD not to recalculate its Medicaid reimbursement rate despite being on notice that the provider had inadvertently submitted inaccurate program and utilization data for its three-day habilitation programs. In addition to refusing to recalculate

a rate that was approximately 55% lower than it should have been, the Department and OPWDD also sought to initiate a retroactive recoupment against the provider, which were alleged to be for excess payments.

The Dutchess County Supreme Court granted a preliminary injunction finding that the recoupment must be stayed in order to lessen the financial stress caused by the Medicaid reimbursement rates that failed to cover the provider's operating costs during a pandemic.<sup>20</sup> Most recently, the Supreme Court held that the OPWDD must recalculate the reimbursement rate to include all three of the provider's day habilitation programs and that no recoupments may be collected against the provider until the recalculation is complete.<sup>21</sup>

Similarly, a licensed operator of day habilitation programs in Westchester County challenged rate determinations as arbitrary, capricious, and an abuse of discretion, contending that OPWDD's reimbursement calculation illegally underfunded its services and programming.<sup>22</sup> Following a dismissal of the petition by the Westchester County Supreme Court, the Appellate Division, Third Department noted that none of the documents submitted by OPWDD contained calculations or back-up data that would allow the court to review and verify the accuracy of OPWDD's summary figures and conclusions. The matter was remitted to the Supreme Court for a new determination after OPWDD was directed to supplement its answer with a full administrative record.

### Self-Directed and Residential Programming Cuts

Other areas of OPWDD programming have also experienced funding cuts during COVID-19. In August 2020, OPWDD implemented a 20% withhold for self-directed services.<sup>23</sup> Self-directed services, which are also offered through the HCBS waiver, provide individuals with developmental disabilities and their families the chance to choose services needed, staff to help provide those services, and when those services should be offered.

OPWDD claimed that the 20% withhold was necessary because of the absence of recovery aid from the federal government to offset the state's losses during COVID-19.<sup>24</sup> OPWDD also warned at the time of the withhold implementation that all or a portion of the withhold could be converted to a permanent reduction. As of February 2021, it was confirmed that the 20% withhold would be converted to a 5% cut.<sup>25</sup> More recently, however, OPWDD informed the provider community that, effective immediately, the agency would cease the withholding of 20% of non-Medicaid Local Assistance payments planned to be made in the current fiscal year and that OPWDD would begin to process full repayment of funds withheld to date.<sup>26</sup> What providers do not know as of this writing is whether a 5% cut will still be implemented effective April 1, 2021, and whether it will be applied directly to the self-directed budgets of individuals and their families.

Since the COVID-19 pandemic, OPWDD has also made cuts to residential habilitation programming that enables individuals with disabilities to remain in the community versus receiving a level of care only offered in a long-term care facility. Generally, a provider that operates supervised residences, or IRAs, receives payment at a provider-specific, daily rate for each resident. This rate compensates providers for their operating costs, including costs related to staffing and providing care to residents, as well as capital costs associated with the physical maintenance of facilities, including room and board.<sup>27</sup>

Some providers, however, have experienced cuts to the room and board piece of the capital cost component that the state has historically represented would be fully reimbursable. In August 2020, an IRA provider challenged a determination by the Department and OPWDD to reduce the capital cost portion of its reimbursement rate—the Room and Board Supplement—by 12%.

Due to the reduction in the supplement, the provider was compelled to divert funds that would normally be used to fund direct care and other resident services during a pandemic. Further, in addition to converting some of its own properties to aid the state in its agreement with the federal government to transform certain institutional levels of services to community-based residential programs, the provider was left to fund those same capital costs that the state had previously assured would be fully reimbursable.<sup>28</sup>

In addition to operating and capital costs, residential habilitation reimbursement rates also account for the fact that residents spend time both in and outside of their supervised residence depending on their plan of care. Generally, residential habilitation providers receive Medicaid reimbursement payments as a result of three different scenarios: a day when supervised IRA staff deliver residential services to the resident either at or outside the supervised residence ("service days"); when the resident is away from the supervised residence and not receiving services, and the absence is for the purpose of visiting with family or friends, or a vacation ("therapeutic leave days"); and when the resident is on medical leave from the residence or when any other institutional or inpatient Medicaid payment is made for providing services to the resident ("retainer days").<sup>29</sup>

On September 28, 2020, CMS approved an amendment to New York's HCBS waiver that resulted in significant cuts to these aspects of provider reimbursement. For one, OPWDD amended the waiver to impose a limit on therapeutic leave days. Before the amendment, there was no limit on the number of days for which a provider could receive reimbursement. Previously, providers were reimbursed for the full daily rate on therapeutic leave days. Prior to the amendment, residential providers were also able to account for the cost providers incur during vacancy days through an "occupancy adjustment."<sup>30</sup> This adjustment would be applied to increase the operating

component of provider-specific rates. Under the amendment, the occupancy adjustment was eliminated.<sup>31</sup> In proposing these amendments and rate cuts, the state relied on rate-setting provisions in the approved 2020–2021 New York State Budget.<sup>32</sup>

Following the approval of these rate cuts by CMS, developmental disability provider agencies, provider coalitions, and family members of individuals with intellectual and developmental disabilities filed an application for a preliminary injunction against the U.S. Secretary of Health and Human Services (HHS) to enjoin their implementation.<sup>33</sup> Provider coalitions maintained that the cuts leave vulnerable individuals and their families in a state of uncertainty as medical attention for this population becomes especially critical during COVID-19.

Thereafter, the government filed a combined motion to dismiss and opposition to the motion for a preliminary injunction. On February 10, 2021, the federal district court denied the provider’s request for a preliminary injunction and dismissed the action because New York State was not named as a necessary party. Whether the action will be re-initiated in a New York State forum remains to be seen.

### What Does This Precedent Mean for Providers?

The legal precedent discussed in this article assists providers in establishing that they are entitled to at least a certain level of Medicaid reimbursement in order to provide adequate services to beneficiaries. Depending on the provider type and factual circumstances, adequate levels can be defined as those that cover the provider’s cost of providing high-quality services or declaring that a change in methodology by the Department or OPWDD is not legally substantiated.

In addition to the impact of Medicaid rates on providers, reimbursement rate issues significantly influence the care received by those that receive Medicaid services. Cuts of a certain magnitude can dramatically limit access to care that beneficiaries need—whether it be for financial reasons or because services can no longer be offered by the provider due to their rate being unsustainably low. For this reason, when seeking injunctive relief, providers should highlight the quality of their services provided, the number of individuals served, and the breadth of impact should those services cease to exist. This is especially persuasive when a provider is located in a more rural area and there is a dearth of similar services to offer beneficiaries should providers be unable to financially sustain their operations.

While there is solid legal footing for challenging the state’s rate-setting methodologies, the stretched New York State budget makes it likely that the provider community will continue to see additional cuts, withholds, and fiscal changes to their programming and services as the COVID-19 pandemic—and its financial aftermath—continue to develop.

### Endnotes

1. See N.Y. Soc. Serv. Law § 363-a (Consol. 2021); see also N.Y. Pub. Health Law § 201(1)(v) (Consol. 2021).
2. N.Y. Pub. Health Law § 201(1)(o) (Consol. 2021); N.Y. Pub. Health Law § 201(1)(p) (Consol. 2021).
3. N.Y. Soc. Serv. Law § 363 (Consol. 2021).
4. *LeadingAge N.Y., Inc. v. Shah*, 58 N.Y.S.3d 651, 660 (N.Y. App. Div. 2017).
5. *AAA Medical Equipment, Inc. v. Zucker*, Index No. 506392/2017 (N.Y. Sup. Ct., Oct. 18, 2018).
6. *The Consumer Directed Personal Assistance Association of New York State v. Zucker*, Index No. 904696-19 (N.Y. Sup. Ct., Oct. 11, 2019). The decision was subsequently appealed to the New York Appellate Division, Third Department, and the record has not yet been perfected due to motions to extend time to do so.
7. *LeadingAge N.Y., Inc. v. Zucker*, Index No. 907319-19 (N.Y. Sup. Ct., Jan. 19, 2021); *Autumn View Health Care Facility, LLC v. Zucker*, Index No. 907446-19 (N.Y. Sup. Ct., Jan. 19, 2021); *Mayfair Care Center Inc. v. Zucker*, Index No. 907781-19 (Sup. Ct., Jan. 19, 2021).  
On November 7, 2019, the *Mayfair Care Center, Inc. v. Zucker* proceeding and action was commenced as litigation also related to *LeadingAge*. By Order dated January 13, 2020, the Supreme Court granted plaintiffs-petitioners’ motion to consolidate *Autumn View* and *LeadingAge* to the extent of having both cases proceed under a unified briefing schedule and toward a joint trial.
8. See N.Y. Mental Hyg. Law § 13.01 (Consol. 2021).
9. See N.Y. Mental Hyg. Law §§ 43.02(2)(e)(ii) & 13.09(b); see also N.Y. Comp. Codes R. & Regs. tit. 10, § 86-10 (West 2021); N.Y. Comp. Codes R. & Regs. tit. 14, §§ 635-1 & 641-1 (West 2021).
10. *Chauatauqua County Ch. of NYSARC Inc. v. Delaney*, 95 N.Y.S.3d 124 (N.Y. Sup. Ct. 2018).
11. New York State Department of Health, *Home and Community-Based Services Waiver*, [https://www.health.ny.gov/health\\_care/medicaid/program/longterm/omrdd.htm](https://www.health.ny.gov/health_care/medicaid/program/longterm/omrdd.htm) (last accessed March 16, 2021).
12. See 42 U.S.C.S. § 1396 (LexisNexis 2021).
13. <https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/Waiver-Descript-Factsheet/NY>.
14. *Supra*, n. 11 at at 68.
15. N.Y. Comp. Codes & Regs. tit. 14, § 635-10.4(b) (West 2021).
16. *Id.*
17. N.Y. Comp. Codes & Regs. tit. 14, § 635-10.3 (West 2021); see also Office of People With Developmental Disabilities, *ICF/IID Level of Care Eligibility Determination Form* (Jan. 2020).
18. *Id.*
19. *Disability Advocates Urge Cuomo to Reconsider Budget Cuts*, <https://news.wbfo.org/post/disability-advocates-urge-cuomo-reconsider-budget-cuts> (last accessed March 16, 2021).
20. *In Flight, Inc. v. Kastner*, Index No. 2020-80005 (N.Y. Sup. Ct., Feb. 19, 2021).
21. *Id.*
22. *Richmond Children’s Ctr. Inc. v. Delaney*, 138 N.Y.S.3d 748 (N.Y. App. Div. 2021).
23. New York State Office for People with Developmental Disabilities, [https://content.govdelivery.com/attachments/NYOPWDD/2020/08/21/file\\_attachments/1523820/20%25%20Withhold%20Memo%20-%20Final%20-%202008-21-20.pdf](https://content.govdelivery.com/attachments/NYOPWDD/2020/08/21/file_attachments/1523820/20%25%20Withhold%20Memo%20-%20Final%20-%202008-21-20.pdf) (last accessed March 16, 2021).
24. *Id.*
25. New York Association of Psychiatric Rehabilitation Services, Inc., <https://www.nyaprs.org/e-news-bulletins/2021/1/19/cuomo->

5-cuts-to-state-aid-15-of-withholds-restored-will-sue-feds-if-is-insufficient-creation-of-office-of-addiction-amp-mh-services (last accessed March 16, 2021).

26. New York State Office for People with Developmental Disabilities, *Local Assistance Payment Withhold—Update* (Feb. 24, 2021), [https://content.govdelivery.com/attachments/NYOPWDD/2021/02/24/file\\_attachments/1705262/20%25%20Withhold%20Cessation%20and%20Repayment%20Memo%20-%202002-24-20.pdf](https://content.govdelivery.com/attachments/NYOPWDD/2021/02/24/file_attachments/1705262/20%25%20Withhold%20Cessation%20and%20Repayment%20Memo%20-%202002-24-20.pdf).

27. N.Y. Comp. Codes & Regs. tit. 14, § 641-1.3 (West 2021); *see also* N.Y. Comp. Codes & Regs. tit. 14, § 641-1.2 (West 2021).

28. *See Opengate, Inc. v. Kastner*, Index No. 2020-52343 (commenced Aug. 7, 2020). A decision on the merits of the provider’s petition is currently pending.

29. 2019 Home & Community Based Services Waiver Amendment, Addendum A(I)(dd), (gg), and (cc) at 316.

30. 2019 Home & Community Based Services Waiver Amendment, Addendum A(I)(t) at 316.

31. *NYS OPWDD Comprehensive Waiver*, <https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/82681> (last accessed March 16, 2021).

32. *OPWDD Response to Public Comments Received June 1, 2020-July 1, 2020 on the OPWDD 1915(c) Comprehensive Home and Community-Based Services (HCBS) Waiver Draft October 1, 2020 Amendment*, [https://opwdd.ny.gov/system/files/documents/2020/10/response-to-public-comment-oct-2020-amend\\_accessible.pdf](https://opwdd.ny.gov/system/files/documents/2020/10/response-to-public-comment-oct-2020-amend_accessible.pdf) (last accessed March 16, 2021).

33. *Cerebral Palsy Association of Nassau County, Inc. v. Cochran*, 20-cv-3718 (D.D.C. Feb. 10, 2021).



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# The Health Law Section Presents an Updated NYSBA Family Health Care Decisions Act Resource Center

This Resource Center designed to help New Yorkers understand and implement the Family Health Care Decisions Act—the law that allows family members to make critical health care and end-of-life decisions for patients who are unable to make their wishes known.

The Resource Center has been revised to include:

- Current text of the FHCDA, as amended, and related statutes.
- A summary of amendments since enactment.
- Updated FAQs.
- A list of law journal articles about the FHCDA.
- And more!

Visit the FHCDA Resource Center at <https://nysba.org/fhcda-resource-center/>.

Our warm thanks to Robert N. Swidler, Esq., and Jorge L. Rivera, Esq., for bringing the Resource Center up to date.

## Family Health Care Decisions Act Summary of Key Provisions

2020 Update by Robert N. Swidler and Jorge L. Rivera

*Reproduced from the NYSBA Family Health Care Decisions Act Resource Center.  
Available at <https://nysba.org/fhcda-resource-center/>*

It has been ten years since the enactment of the Family Health Care Decisions Act (FHCDA).<sup>1</sup> The FHCDA establishes the authority of a patient's family member or close friend to make medical treatment decisions for the patient in the event the patient lacks capacity to make such decisions personally and did not previously make such decisions or appoint a health care agent.

Key provisions of the FHCDA, as amended through 2020, are summarized below.

Note that the FHCDA is detailed, and this summary does not cover all its provisions.

In sum, the FHCDA:

### Definitions

Defines terms used in the FHCDA,

A key recently added term is “attending practitioner” which means “a physician, nurse practitioner or physician assistant, selected by or assigned to a patient pursuant to hospital policy, who has primary responsibility for the treatment and care of the patient.”<sup>2</sup>

### Applicability

Applies to decisions for incapable patients in general hospitals and residential health care facilities (nursing homes).<sup>3</sup> The term “hospital” is used to apply to both those settings.<sup>4</sup>

- Does not apply to decisions for incapable patients:
  - who have a health care agent;<sup>5</sup>
  - who have a court-appointed guardian under SCPA 1750-b;<sup>6</sup>
  - for whom decisions about life-sustaining treatment may be made by a family member or close friend under SCPA 1750-b;<sup>7</sup>
  - for whom treatment decisions may be made pursuant to OMH or OPWDD surrogate decision-making regulations.<sup>8</sup>

### Determining Incapacity

- Sets forth a hospital-based process to determine that a patient lacks decisional capacity for purposes of

the FHCDA.<sup>9</sup> It involves an initial determination by the attending practitioner, and a concurring determination by a “health or social service practitioner.”

- Requires that practitioners who determine whether a patient lacks capacity as a result of intellectual disability or mental illness must possess special credentials.<sup>10</sup>
- Requires that the patient and prospective surrogate be informed of the determination of incapacity.<sup>11</sup>
- Requires additional notifications for patients from mental hygiene facilities.<sup>12</sup>
- Provides that if the patient objects to the determination of incapacity, or the choice of surrogate, or the surrogate’s decision, the patient’s objection prevails unless a court find that the patient lacks capacity, or another legal basis exists for overriding the patient’s decision.<sup>13</sup>

### Decisions for Adult Patients by Surrogates

- Sets forth, in order of priority, the persons who may act as a surrogate decisionmaker for the incapable patient, i.e.:<sup>14</sup>
  - an MHL Article 81 court-appointed guardian (if there is one, and if empowered by the court order to make health care decisions);
  - the spouse or domestic partner (as defined in the FHCDA);
  - an adult child;
  - a parent;
  - an adult brother or sister;
  - a close friend.
- Grants the surrogate authority to make all health care decisions for the patient that the adult patient could make for himself or herself, subject to certain standards and limitations.<sup>15</sup>
- Provides that a surrogate’s consent is not required if the patient already made a decision about the proposed health care, expressed orally or in writing or, with respect to a decision to withdraw or withhold life-sustaining treatment expressed either orally during hospitalization in the presence of two witnesses or in writing.<sup>16</sup>
- Requires the surrogate to decide about treatment based on the patient’s wishes, including the patient’s religious and moral beliefs, or, if the patient’s wishes are not reasonably known and cannot with reasonable diligence be ascertained, based on the patient’s best interests.<sup>17</sup>

- Authorizes surrogate decisions to withhold or withdraw life-sustaining treatment if the treatment:
  - would be an extraordinary burden to the patient and the patient is terminally or permanently unconscious, or
  - if the patient has an irreversible or incurable condition and the treatment would involve such pain, suffering or other burden that it would reasonably be deemed inhumane or excessively burdensome under the circumstances.<sup>18</sup>
- Inasmuch as the definition of life-sustaining treatment includes decisions about resuscitation, this standard would apply to a surrogate decision to enter a DNR order as well.<sup>19</sup>

### Decisions for Minor Patients

- Authorizes the parent or guardian of a minor patient to decide about life-sustaining treatment, in accord with the same standards that apply to surrogate decisions for adults.<sup>20</sup>
- Requires the parent or guardian to make the decision in accordance with the minor’s best interests, taking into account the minor’s wishes as appropriate under the circumstances.<sup>21</sup>
- If the attending practitioner determines that the minor has the capacity to decide about life-sustaining treatment, requires the minor’s consent to withhold or to stop treatment.<sup>22</sup>
- If there is another parent who is unaware of the decision, requires an attempt to inform such parent of the decision.<sup>23</sup>
- Allows an attending practitioner to accept a life-sustaining treatment decision by an emancipated minor without parental consent, although a decision by the minor to forgo such treatment requires ethics review committee approval.<sup>24</sup>

### Decisions for Adult Patients Without Surrogates

- Establishes a procedure for making health care decisions, other than life-sustaining treatment decisions, for adult patients who have lost decision making capacity and have no available family member or friend to act as a surrogate.<sup>25</sup>
- Requires hospitals, after a patient is admitted, to determine if the patient has a health care agent, guardian, or a person who can serve as the patient’s surrogate. If the patient has no such person, and lacks capacity, the hospital must identify, to the extent practical, the patient’s wishes and preferences about pending health care decisions.<sup>26</sup>

- Authorizes the attending practitioner to decide about routine medical treatment for patients without surrogates.<sup>27</sup>
- For decisions about major medical treatment, the attending practitioner must consult with other health care professionals directly involved with the patient's care and a second practitioner selected by the hospital or nursing home must concur in the decision.<sup>28</sup>
- A decision to withdraw or withhold life-sustaining treatment can be made either (a) by a court, in accordance with the FHCDA surrogate decision making standards, or (b) the attending practitioner and a second practitioner determine that the treatment offers the patient no medical benefit because the patient will die imminently, even if the treatment is provided, and the provision of the treatment would violate accepted medical standards.<sup>29</sup>
- diminish the duty of parents to consent to treatment for minors.<sup>38</sup>
- Provides that a hospital or attending practitioner that refuses to honor a health care decision made by a surrogate in accord with the standards set forth in the FHCDA is not entitled to compensation for treatment provided without the surrogate's consent, except under specified circumstances.<sup>39</sup>

### Resuscitation-related Provisions

- Eliminates much of New York's DNR Law as applied to hospitals and provides for DNR decision-making in hospitals in accordance with the standards and procedures in the FHCDA.<sup>40</sup>
- Creates a new PHL Article 29-CCC as a place to retain (with some modifications) existing provisions on nonhospital DNR orders.<sup>41</sup>
- Obligates home care agency staff and hospice staff to honor nonhospital DNR orders (previously, non-hospital DNR orders were directed only to emergency medical services and hospital personnel).<sup>42</sup>
- Renames the former DNR law, PHL Article 29-B, as "Orders Not to Resuscitate for Residents of Mental Hygiene Facilities" in order to preserve existing authorization for and rules regarding DNR orders in those settings.<sup>43</sup>

### Other FHCDA Provisions

- Requires hospitals and nursing homes to establish or participate in an ethics review committee that meets certain standards (e.g., multidisciplinary membership).<sup>30</sup>
- The committee would provide advice upon request or in the event of disputes and review certain sensitive surrogate decisions.<sup>31</sup>
- Sets forth the right of private hospitals and individual health care providers to refuse, on grounds of moral or religious conscience, to honor health care decisions made pursuant to the FHCDA, subject to limits and requirements (e.g., the facility must notify patients of its policy prior to admission, and promptly transfer responsibility for the patient to another health care professional or hospital willing to honor the decision).<sup>32</sup>
- Protects surrogates, health care providers and ethics committee members from civil and criminal liability for acts performed in good faith pursuant to the FHCDA.<sup>33</sup>
- Provides that liability for the cost of health care provided to an adult patient under the FHCDA is the same as if the patient had consented to treatment.<sup>34</sup>
- Establishes that the FHCDA does not:
  - expand or diminish any authority an individual may have to express health care decisions for himself or herself;<sup>35</sup>
  - affect existing law concerning implied consent to health care in an emergency;<sup>36</sup>
  - permit or promote suicide, assisted suicide, or euthanasia;<sup>37</sup>

### Health Care Proxy Law Amendments

- Amends the Health Care Proxy Law:
  - to require provider, when an agent directs the provision of life-sustaining treatment, either to provide the treatment, transfer the patient, or seek judicial review;<sup>44</sup>
  - to adopt the FHCDA provisions regarding institutional and health care provider conscience provisions.<sup>45</sup>

### Conforming Amendments to MHL Article 81 and the Health Care Decisions Act (SCPA 1750-b)

- Authorizes an MHL Article 81 guardian of the person to act as a surrogate under the FHCDA for decisions in hospitals.<sup>46</sup>
- Repeals provisions in MHL Article 81 that restrict the authority of a guardian to make life-sustaining treatment decisions.<sup>47</sup>
- Amends the Health Care Decisions for Persons Who Are Intellectually Disabled (SCPA § 1750-b) to insert a definition of "life-sustaining treatment."<sup>48</sup>
- Amends SCPA § 1750-b to allow the Willowbrook Consumer Advisory Board to act as the guardian for class members.<sup>49</sup>



## Task Force Special Committees

- Directs the NYS Task Force on Life and the Law to create a special committee, with half of its members appointed by OPWDD and OMH, to provide advice on standards and procedures for surrogate decision making for persons with MI/DD, and persons in mental health facilities.<sup>50</sup>
- Directs the NYS Task Force on Life and the Law to make recommendations on extending FHCDA decision making standards and procedures to other settings, such as physicians' offices and home care.<sup>51</sup>

## Effective Date

- Hospitals were required to implement the FHCDA by June 1, 2010, but effective immediately hospitals were permitted to adopt and follow policies that are consistent with the FHCDA standards and procedures.<sup>52</sup>

## Endnotes

1. NY Laws of 2010, Chapter 8.
2. N.Y. Public Health Law § 2994-a.2.
3. N.Y. Public Health Law § 2994-b.1.
4. *Id.*, § 2994-a.16.
5. *Id.*, § 2994-b.2.
6. *Id.*, § 2994-b.3(a).
7. *Id.*, § 2994-b.3(b).
8. *Id.*, § 2994-b.3(c). See 14 N.Y.C.R.R. § 633.11.
9. *Id.*, § 2994-c.
10. *Id.*, § 2994-c.3(c).
11. *Id.*, § 2994-c.4(a),(b).
12. *Id.*, § 2994-c.4(c).
13. *Id.*, § 2994-c.6.
14. *Id.*, § 2994-d.1.
15. *Id.*, § 2994-d.3(i).
16. *Id.*, § 2994-d.3(ii).
17. *Id.*, § 2994-d.4.
18. *Id.*, § 2994-d.5.
19. N.Y. Public Health Law § 2994-a.19.
20. *Id.*, § 2994-e.1.
21. *Id.*, § 2994-e.2(a).
22. *Id.*, § 2994-e.2(b).
23. *Id.*, § 2994-e.2(c).
24. *Id.*, § 2994-e.3.
25. *Id.*, § 2994-g.
26. *Id.*, § 2994-g.1.
27. *Id.*, § 2994-g.3.
28. *Id.*, § 2994-g.4.
29. *Id.*, § 2994-g.5.
30. *Id.*, § 2994-m.
31. *Id.*, § 2994-m.2.
32. *Id.*, § 2994-n.
33. *Id.*, § 2994-o.
34. *Id.*, § 2994-p.
35. *Id.*, § 2994-q.1.
36. *Id.*, § 2994-q.2.
37. *Id.*, § 2994-q.3.
38. *Id.*, § 2994-q.4.
39. *Id.*, § 2994-s.
40. See Chapter 8, Laws of 2010, § 4, which amends N.Y. Public Health Law Article 29-B the DNR law to make it applicable only to mental hygiene facilities. See also new N.Y. Public Health Law § 2994-a.19, which defines "life-sustaining treatment" to include cardiopulmonary resuscitation (CPR). See also FHCDA § 4, which amends N.Y. Public Health Law Article 29-B (the DNR law) to make it applicable only to mental hygiene facilities.
41. See N.Y. Public Health Law § 2994-aa et seq.
42. N.Y. Public Health Law § 2994-ee.
43. See n. 40.
44. N.Y. Public Health Law § 2984.3.
45. N.Y. Public Health Law § 2984.5.
46. N.Y. Mental Health Law (MHL) § 81.22.8.
47. MHL § 81.22.9(e).
48. MHL § 81.22.9(e). See SCPA § 1750-b.1.
49. Chapter 8, Laws of 2010, § 25, repealing MHL § 81.22.9(e). See SCPA § 1750-b.1.a.
50. Chapter 8, Laws of 2010, § 28.1.
51. Chapter 8, Laws of 2010, § 28.2. The NYS Task Force on Life and the Law delivered its recommendations on June 21, 2016. The recommendations called to amend the FHCDA and the Health Care Decisions Act (HCDA) to clarify and streamline the relevant decision-making processes while preserving certain protections in existing law specific to persons with developmental disabilities and patients in or transferred from mental health facilities. New York State Task Force on Life and the Law—Special Advisory Committee, 2016. 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. [online] New York: New York State Department of Health. [https://www.health.ny.gov/regulations/task\\_force/reports\\_publications/docs/2016-06\\_recommendations\\_for\\_amending\\_fhcda.pdf](https://www.health.ny.gov/regulations/task_force/reports_publications/docs/2016-06_recommendations_for_amending_fhcda.pdf) [Accessed 8 November 2020]. Also, please see Paul R. Kietzman, *A Bridge for People with Developmental Disabilities: The FHCDA and the HCDA/PMR Need Some Reconciliation*, 16 NYS Bar Assn Health L. J. 90 (2011); Robert N. Swidler, *Surrogate Decision Making for Incapable Adult Patients with Mental Disabilities: A Chart of Applicable Laws and Regulations*, 16 NYS Bar Assn Health L. J. 93 (2011); Kathryn Jerian & John Dow, *New York's "Black Hole" of Surrogate Decision-Making for Individuals with Intellectual and Developmental Disabilities Without Capacity*, 23 NYS Bar Assn Health L. J. 59 (2018); and Robert N. Swidler, *The Family Health Care Decisions Act Should Apply to End-of-Life Decisions for Persons Who Are Intellectually Disabled*, 23 NYS Bar Assn Health L. J. 64 (2018).
52. Chapter 8, Laws of 2010, § 29.

# Medical Aid is Dying in New York State: A Survey of Health Care Professionals to Inform Legislation

By Jonathan Steinberg, Phoebe Friesen, Ari Kirshenbaum and Brendan Parent

## Abstract

### Background

A proposal for legalizing Medical Aid in Dying (MAID) in New York State (NYS) is currently being considered in the Assembly and the Senate. Detailed evidence related to the attitudes of health care professionals in the state towards the practice has not been collected since the late 1990s with the exception of a 2018 Medscape survey of physicians including many across the state, which showed majority support for MAID and support for the Medical Aid in Dying Act by a three to one margin. We sought to perform an updated and more detailed survey of health care professionals on this topic.

### Methods

Health care professionals in the state were contacted via email with a link to the survey. Respondents were first asked if MAID is ever ethically permissible. Those who selected “Never” were directed to questions about their concerns related to the practice. Those who selected “Under Certain Circumstances” or “Always” were randomized into either the Questionnaire or Vignette arm of the survey and were first asked questions about various requirements related to MAID, followed by questions about their concerns and motivations related to legalizing the practice.

### Results

Most of the 111 respondents who completed the entire survey were physicians (49%), female (65%), and/or white (79%). Of the 131 participants who completed the initial question, 85% believed that MAID was at least sometimes permissible, while 15% believed that it was never permissible. Those who thought it was never permissible were most concerned about slippery slope arguments and that MAID might violate religious or professional oaths, while those that thought it was at least sometimes permissible were motivated to legalize the practice in order to relieve extreme suffering and to ensure a patient’s dignity at the end of life. Compared to those in the Questionnaire arm, those in the Vignette arm found requiring a minimum age, state residency, or a minimum waiting period as less important, while both groups saw palliative care considerations and psychiatric consultations as very important.

### Conclusions

This survey supports other data that suggest increasing acceptance of MAID among health care professionals—specifically in New York State—since the 1990s,

though additional larger scale studies are needed. It is possible that modifications to standard legal requirements related to age, residency, waiting period and palliative care would be accepted by the medical community and would promote ethical and fair access to MAID.

### Keywords

Medical Aid in Dying, New York State, Restrictions, Safeguards, Framing Effects

## Background

### Medical Aid in Dying: Legal Status and Evidence

Medical Aid in Dying (hereafter MAID) is a process through which a medical professional provides a competent, terminally ill adult patient with a prescription for a cocktail of medications, upon the patient’s request, which the patient may take, and must self administer to end his or her own life. Legislation that permits MAID has now been passed in eight states—Oregon, Washington, California, Vermont, Colorado,, Hawaii, New Jersey and Maine—and in Washington D.C. The laws governing MAID in each of these states require patients to have a terminal diagnosis (less than six months to live), have state residency, to be a minimum 18 years of age, and to make at least two oral requests (generally, at least 15 days apart) as well as one written. In all cases, a physician writes a prescription for a cocktail of pills, which the patient can then choose to fill and ingest at any point afterwards in order to end his/her life. The practice is also *de facto* legal via Supreme Court decision in Montana.

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**Jonathan Steinberg (corresponding author):** Jackson Memorial Hospital Internal Medicine Program, 1611 NW 12th Ave, Suite Central 600-D, Miami, FL 33136, [jonathan.steinberg@jhsMiami.org](mailto:jonathan.steinberg@jhsMiami.org).

**Phoebe Friesen:** Biomedical Ethics Unit, Department of Social Studies of Medicine, McGill University, 3647 Peel St, Montreal, QC, H3A 1X1, [phoebe.friesen@mcgill.ca](mailto:phoebe.friesen@mcgill.ca)

**Ari Kirshenbaum:** Saint Edmund’s Hall, Saint Michael’s College, 22 Campus Road, College Pkwy, Colchester, VT 05439 [akirshenbaum@smcvt.edu](mailto:akirshenbaum@smcvt.edu).

**Brendan Parent:** Division of Medical Ethics, NYU School of Medicine, 227 East 30th Street, Floor 7, New York, NY 10016, [brendan.parent@nyu.edu](mailto:brendan.parent@nyu.edu).

Several other countries, including the Netherlands, Belgium, Switzerland, Luxembourg, Colombia, and Canada, have also legalized similar practices. There is substantial variation in both who is responsible for administering the medication (patients, physicians, nurse practitioners), as well as in what situations the practice is permissible in these countries, some of which allow hastening death on the basis of psychiatric suffering, as well as physical suffering without a terminal diagnosis.<sup>1</sup>

Evidence from Oregon and Washington suggests that demographics that predict utilization of MAID include being white, having a college education, being over 65, and having a diagnosis of cancer.<sup>2,3</sup> Despite increasing rates in Oregon, the percentage of eligible individuals who requested a prescription to hasten their deaths in 2015 remained quite low, at 0.64%, while the percentage of those who actually filled the prescription and took the medications in order to end their lives was even smaller, at 0.39%.<sup>2</sup>

### Legal Status of Medical Aid in Dying in New York State

About 30 states are now considering MAID legislation, among which New York State is arguably one of the most influential. New York State has been considering MAID legislative proposals for several years, with the most recent being a bill in the Assembly (A4321). The bill has not yet been introduced in the Senate for the 2021-22 legislative session. The justification for the bill includes references to the Brittany Maynard case from Oregon in 2014, whose advocacy helped lead to legalization in California, and references to recent New York State survey polls demonstrating strong support for MAID among New Yorkers.<sup>4</sup> The bills largely mirror the requirements of laws in other states, with at least two significant exceptions: New York's proposal requires neither a waiting period, nor state residency. The New York Court of Appeals recently dismissed the long-running MAID case *Myers v Schneiderman*, brought by patients, doctors, and an advocacy organization, implying that this issue is better determined by the Legislature.

As New York considers whether and how to legalize MAID, it has carefully considered the experiences of states where the practice is legal and the perspectives of New York stakeholders through legislative hearings. The investigators believe that legislation should be in part informed by the perspectives of practicing health care professionals who will be responsible for providing medical care to, assessing patient eligibility for, and writing prescriptions for, MAID Medications for the practice to be implemented.

### Attitudes Towards Medical Aid in Dying

Demographic and contextual features that predict support or opposition to the practice have also been reported. Religiosity appears to predict opposition to both physician-assisted suicide (term used in cited studies, which this article refers to as MAID) and terminal palliative care,<sup>5,6,7,8,9</sup> while legality in a country leads to higher rates of support.<sup>10,11,12,13,14</sup> Several specific factors have been found to influence degrees of support for the prac-

tice. The form of administration makes a difference, as shown by evidence that health care professionals consistently are found to be more in favor of MAID (in which the patient is responsible for administering the intervention that ends their life) than euthanasia (in which the physician administers the intervention).<sup>15,16,17</sup> Palliative sedation is consistently thought to be more acceptable than either MAID or euthanasia.<sup>5,18</sup> More support is expressed for the practice when the request is coming from an older person,<sup>19,20,21</sup> when a supportive family or friend is present,<sup>19</sup> and when the basis of suffering is physical rather than psychological,<sup>19,22</sup> particularly if there is a terminal illness present.<sup>23</sup>

Attitudes of health care professionals towards the practice have undergone considerable investigation as well. Most of this research is from nearly two decades ago and involves surveys of physicians, who generally show less support for the practice when compared to the public.<sup>16,24,25</sup> Within research related to the attitudes of physicians, it has been found that specialties that tend to be most supportive include emergency medicine, psychiatry, and general medicine, while geriatrics, oncologists, neurologists, family practitioners, and palliative care specialists tend to be less supportive,<sup>17,13,23</sup> although the American Academy of Family Physicians has a position of engaged neutrality. Other research involving health care professionals has found that medical students support MAID more than physicians, and social workers are more in favor than either physicians or nurses.<sup>6,18</sup> This investigation will add to the existing body of attitude surveys, focusing specifically on New York State health care professionals, including physicians, nurses, and social workers, and their views toward specific legislative requirements.

### Attitudes in in New York State

A barrier towards implementing legislation in New York is the fact that the attitudes of health care professionals in the state have not been specifically examined since the late 1990s, when three surveys were conducted.<sup>6,20,23</sup> The first of these involved a survey of 100 gerontological nurses and found that 46% thought that physician-assisted suicide should be legalized for all individuals regardless of age, while 58% thought it should only be available to the elderly.<sup>20</sup> In another survey of 1,137 health care professionals, it was found that social workers were significantly more likely to express support for the practice than either physicians or nurses. Conversely, religious belief, empathy, knowledge of symptom management, and less concern for analgesic toxicity predicted opposition to the practice.<sup>6</sup> Finally, in a survey of 111 primary care physicians, only 31% agreed with the statement "I support legislation to legalize physicians-assisted suicide under certain circumstances," while 48% disagreed and 21% were uncertain. Interestingly, while no difference arose in terms of their support for the practice, a significantly smaller proportion of male vs. female physicians (57% to 89%) endorsed the statement "suicide can be 'rational'

under certain circumstances.”<sup>23</sup> A 2020 Medscape survey of clinicians across the U.S. demonstrated significant support for MAID.<sup>24</sup> We sought to build on these findings and update the available evidence concerning the attitudes of health care professionals specifically in New York State towards the practice, now that there are over two decades of experience with MAID in Oregon, a decade of experience in Washington, and years of experience in other states.

## Methods

### Design

This study was a cross sectional observational survey design with convenient sampling of NYS health care professionals, approved by the New York University School of Medicine Institutional Review Board (Study ID i17-00264). A survey requiring approximately 15 minutes or less to complete was designed with Qualtrics. All participants were first asked to complete a short section of questions related to demographic and professional information. Each participant was then asked about the ethical permissibility of MAID, selecting from “Never,” “Under certain circumstances,” and “Always.” Those who chose “Never” were directed to questions about their concerns related to the practice. Those who chose either “Under certain circumstances” or “Always” were randomized into one of two survey arms. The first arm (hereafter the “Questionnaire Arm”) asked participants about the importance of various restrictions and safeguards, followed by sections on motivations and concerns they have in relation to MAID. The second arm (hereafter the “Vignette Arm”) also asked participants about the importance of specific restrictions and safeguards, but through the use of five fictional patient vignettes, each followed by three sub-questions, with the sets of sub-questions randomized to different vignettes for each participant. See Figure 1 for details of the survey flow.

### Sampling

A clearinghouse was used to distribute a consent letter including the survey link via e-mail to registered health care professionals across New York State. Neither the clearinghouse nor the researchers collected any personally identifiable information from consenting participants, and the clearinghouse was not otherwise involved in the research process. In addition, the investigators contacted leadership at eight major hospital centers in New York City, Syracuse, Albany, and Buffalo who agreed to distribute the survey link to physicians and nurses in their networks.

## Results

### Population

Overall, 131 responses were collected; 111 participants completed the entire survey specific to their study arm, with an additional 20 completing at least the primary question on the ethical permissibility of MAID. Nearly half of the participants were physicians (49%), while 37% were nurses and 13% were social workers. The majority were female (65%), white (79%), and worked in a hospital

(60%), and there was a wide distribution according to age and years in practice. See Table 1 for detailed description of participant demographics.

### Permissibility of MAID

Of the 131 respondents who responded to the question on the general ethical permissibility of MAID, 15% (n= 20) responded “Never,” 69% (90) responded “Under Certain Circumstances,” and 16% (21) responded “Always.” Consequently, 85% (111) believed that MAID was ethically permissible at least under certain circumstances, and were randomized to either the questionnaire or vignette arm. For the purposes of the below analysis, “at least somewhat permissible” or “at least somewhat important” or “at least somewhat concerned” or “at least somewhat motivated,” where applicable, will always refer to greater than or equal to four on a seven-point Likert Scale.

While 21.6% of physicians responded that MAID is never permissible, only 4.5% of nurses did. Additionally, 24.4% of men selected “Never” compared to only 10.5% of women. A hierarchical multiple regression was performed to determine which personal characteristics were most predictive of ethical opposition to MAID. The result revealed that gender accounted for a significant portion of the overall variability in ethical support, with those identifying as female being significantly more likely to respond that the practice is permissible ( $R^2 = 0.05$ ,  $F(1,121) = 5.87$ ,  $p < 0.05$ ). Males identifying as having frequent religious attendance were most likely to report their disapproval of MAID. Type of profession (physician vs. nurse) as a variable was excluded from the regression model because a sizable portion of respondents failed to identify in either category.

### Questionnaire Arm

Overall, 48 participants were randomized to the questionnaire arm, and were asked about the importance of various restrictions and safeguards related to MAID.

Over half of the participants randomized to the questionnaire expressed support for all but one of the MAID restrictions we asked about. Nearly three-quarters of participants (72.9%) believed requiring a minimum age for MAID was at least somewhat important. Of those participants, 85.7% thought the age should be 18 years or older. Similarly, 87.5% believed it was at least somewhat important to require a waiting period between the initial request for MAID and the second request. Of those participants, 65.9% thought the waiting period should be at least two weeks or longer. The majority of participants (93.8%) believed it was at least somewhat important for the patient to consult a palliative care specialist, while 89.6% thought they should at least be referred to a palliative care specialist, and 83.3% thought the patient should attempt a palliative care measure before being permitted to request MAID. Regarding a state residency requirement (that the patient must be a resident of the state where the prescription is written and filled), only 56.3% of participants believed it was at least somewhat important.

The vast majority (95.8%) of participants believed it was at least somewhat important for the primary physician to perform a baseline assessment of decision-making capacity. The vast majority also believed it was at least somewhat important for a psychiatrist to confirm capacity if the patient had a psychiatric history, while 81.3% believed that obtaining baseline confirmation of capacity by a psychiatrist for all patients was at least somewhat important (though no specific detail regarding psychiatric history was given in this question). Regarding terminality and prognosis, 87.5% believed it was at least somewhat important to require a terminal diagnosis, and 78.6% believed the prognosis should be six months or longer to live. Additionally, 95.8% believed it was at least somewhat important to have an in-person translator if the physician and patient speak different primary languages; 91.6% to have the prognosis confirmed by two physicians; 81.3% to require a final attestation within 48 hours prior to self-administration of the MAID drugs; 75.0% to require the patient to make the initial request and forbid the physician from recommending MAID; 54.2% to have spousal agreement; and only 45.8% to have family agreement.

### Vignette Arm

Fifty-one participants were randomized to the vignette arm, with eight not fully completing the section. Participants were first presented with an age-specific vignette (randomized to one of four vignettes) followed by three age sub-questions, and then presented with four general vignettes randomized to sub-questions regarding state residency, waiting period, palliative care, and psychiatric evaluation (see Appendix 1 for details of these four vignettes). All vignettes were controlled for age greater than 18 (except the age-specific vignettes), New York State residency, a prognosis of less than six months confirmed by two physicians, palliative care consultation, and a waiting period of two weeks. To assess the general permissibility of MAID in the baseline vignette, the vignette for William Thompson was selected; 86.0% of participants found MAID to be at least somewhat permissible in this case.

Interestingly, participants in the vignette arm appeared less concerned about adhering to certain standard legal MAID restrictions in comparison to concern expressed in the questionnaire arm. In terms of age, 80.4% of respondents believed it was at least somewhat permissible to provide MAID to a 17-year-old patient, and 68.6% believed it was at least somewhat permissible if the patient was 13 years old. Additionally, 92.9% believed it was at least somewhat permissible if the 17-year-old patient suffered severe pain and was frequently hospitalized, and 56.8% believed it was at least somewhat permissible if only one parent agreed with the decision. With regards to a waiting period, 69.7% believed it was at least somewhat permissible to provide MAID after only a one-week waiting period, 67.4% after a one-day waiting period, and 65.1% after a single request.

Regarding palliative care, while 86.0% believed it was at least somewhat permissible to provide MAID when palliative care was consulted (as in the baseline vignette), when it was explicitly stated that the patient had consulted palliative care, but no palliative measures were attempted, only 65.1% believed it was at least somewhat permissible. Furthermore, only 46.5% believed it was at least somewhat permissible if the patient was only referred, but explicitly did not consult or attempt palliative care, and 46.5% if the patient was neither referred, consulted nor attempted palliative care.

Concerning state residency, 74.4% believed it was at least somewhat permissible when the patient was not a New York State resident and was only in New York for his/her doctor's visits; 81.4% if the patient was not a resident, but had been living in New York for five years; and 83.7% if the patient was a resident, but had moved within two weeks of being diagnosed.

Finally, with regards to decision-making capacity, 48.8% thought it was at least somewhat permissible to provide MAID to a patient with a history of depression without first obtaining a psychiatric confirmation of capacity; 79.1% if psychiatry confirmed decision making capacity; and 79.1% if the patient had a history of depression and a past suicide attempt, but capacity had been confirmed by a psychiatrist.

### Concerns

All participants were asked to complete a section that involved rating their concerns related to legalizing MAID. Those who had responded "Never" to the initial question regarding the ethical permissibility of MAID were most concerned about legalization starting a slippery slope towards involuntary MAID (80% chose at least somewhat concerned) and violating a moral or religious code (80%) or professional code (75%). Conversely, they were least concerned about malpractice claims (30%), cost (15%), the availability of MAID for those who are unable to self-administer the pills (5%). Those who had selected "Under certain circumstances" or "Always" in response to the initial question concerning ethical permissibility of MAID were most concerned that obtaining fully informed consent might be difficult (36% chose at least somewhat concerned) and that feeling like a burden might lead individuals to consider MAID (19%). Conversely, they were least concerned about costs (9%), and MAID violating a moral or religious code (6%). See figure 2 for detail and comparisons.

### Motivations

Only those who selected "Under certain circumstances" or "Always" to the general ethical permissibility question were asked to complete a section on motivations for seeing the practice legalized. The participants were most motivated to see MAID legalized in order to relieve extreme suffering (74% chose at least somewhat motivated), to ensure a patient's dignity at the end of life

(67%), and to respect individual autonomy regarding end of life decision (50%). They were slightly less motivated to see MAID legalized in order to create space for patients to discuss wanting to die (46%) and to allow patients to control the circumstances surrounding when and how they will die (48%).

## Discussion

### Ethical Permissibility

This survey suggests that support for the practice of MAID has greatly increased among New York State health care providers over the last two decades. While only around half of the participants from the surveys in the late 1990s thought MAID could be ethically permissible, 85% of our participants supported the practice at least under certain circumstances.

### Age

As mentioned above, the majority of respondents in the questionnaire arm believed that MAID access should be restricted to patients age 18 or older. Conversely, vignette respondents were largely willing to grant access to a suffering 17-year-old, or even as young as 13 years old. The New York State legislative proposal would permit access only to adults (18 years or older), and this standard is generally codified in other legal standards of adulthood. MAID is perhaps the most profound expression of autonomy, and a lack of adequate tools to assess a “child’s” ability to give informed consent would suggest that retaining the established, though occasionally arbitrary, cutoff of 18 years old seems prudent at this time.<sup>26</sup> Younger people suffering from terminal illnesses should of course retain full access to alternative palliative measures.

### Waiting Period

The vignette respondents appeared to demonstrate greater waiting period leniency, with a majority supporting a waiting period as short as one day or even no waiting period at all. However, the degree of their support decreased as the waiting period decreased. This correlation, coupled with the strong support for a two-week or longer waiting period amongst questionnaire respondents does not comport with the proposed New York legislation, which does not require a waiting period. It can be argued that patients with a terminal diagnosis whose mental or physical suffering cannot be relieved by other measures should not have to wait to receive the prescription, but there is also evidence suggesting that the will to live can fluctuate substantially in dying patients, suggesting a waiting period may be important.<sup>27</sup> It must also be reinforced that receiving the prescription does not require its administration, meaning patients have time to continue considering when and whether to hasten their deaths.

### Residency

Of all the restrictions investigated, requiring state residency garnered the least overall support. Only a slight

majority of questionnaire arm respondents thought it was at least somewhat important, while vignette arm respondents were comfortable providing MAID to a non-resident who had moved to New York State just to receive MAID. The proposed New York bill does not require residency, which may suggest that legislators are unconcerned with, or perhaps willing to entertain the possibility of interstate medical tourism. From an ethical perspective, if the practice is made available then it may not only be appropriate, but also ethically important for New York to make this service available to suffering residents of neighboring states where the practice is prohibited.

### Psychiatric Consultation

In both survey arms, there was strong support for psychiatric confirmation of decision making capacity. In existing state laws and the proposed New York law, a mental health evaluation is only required if the primary or consulting physician is concerned about potential issues with capacity. In Washington and Oregon, this evaluation is triggered if the physician suspects depression or another mental disorder might be interfering with capacity. It is well accepted that any physician is capable of performing an assessment of decision-making capacity, but the challenge is identifying which patients require formal psychiatric evaluation. For example, patients at the end of life frequently experience sadness and a depressed mood, but often this is not true clinical depression, and most experienced physicians should feel comfortable confirming capacity in this situation.<sup>28</sup> However, if the patient has a history of major depression, suicide attempts or suicidal ideation, or another well documented psychiatric condition, consulting a psychiatrist might be the most prudent course of action. A discussion of mental suffering alone as an indication for MAID is beyond the scope of this study.

### Palliative Care

The majority in both study arms agreed that patients should attempt palliative measures before seeking MAID. However, in states where the practice is legal, the patient must only be informed of available palliative therapies; there is no explicit requirement to attempt any measures. The New York bill requires that information and counseling be offered to patients regarding palliative care and end-of-life options appropriate to the patient, including but not limited to: the range of options appropriate to the patient; the prognosis, risks and benefits of the various options; and the patient’s legal rights to comprehensive pain and symptom management at the end of life; and information regarding other appropriate treatment options should the patient wish to initiate or continue treatment.

Palliative therapies, which can include palliative radiation, pain and symptom control, and even palliative surgeries, are known to be effective for many patients. Yet one of the main pushes behind MAID is to elevate patient autonomy. The challenge is how to bolster patient

autonomy, while still promoting the use of palliation, and without distracting from the fact many people in New York State lack access to palliative care.

## Concerns

When analyzing the concerns section, an interesting relationship was noted when comparing the results of those who viewed MAID as “Never” ethically permissible versus those who viewed it as permissible “Under certain circumstances” and “Always.” (Figure 2). While the “Never” group was most concerned that MAID might violate a religious or professional code and start a slippery slope towards involuntary MAID, the “Under certain circumstances” and “Always” group saw these concerns as largely unimportant. This is perhaps reflective of the fact that substantial legal safeguards are clearly delineated in all MAID legislation to prevent misuse of the practice, and that the practice as a whole constitutes essentially a negligible amount of total deaths among patients eligible to receive MAID.<sup>2</sup> Conversely, while the “Under certain circumstances” and “Always” group was most concerned about the cost of MAID and its availability to those who are unable to self-administer medications, the “Never” group saw these concerns as largely unimportant. These differences reflect the polarizing debate surrounding MAID in the United States. Some arguing against the practice focus on the importance of the Hippocratic oath and the sanctity of life,<sup>29</sup> while some in favor acknowledge the challenges of ensuring safe use and fair access.<sup>30</sup>

## Motivations

The relief of suffering and ensuring a patient’s dignity were chosen by the majority of respondents as the most important motivations for legalizing MAID, while making space for talking about dying and giving patients control over the circumstances of their death were considered only slightly less important. Evidence from Oregon suggests that when those interested in seeking MAID are asked about their reasons for wanting to die, they tend to emphasize the importance of retaining control over their death as well as a decline in both independence and quality of life, and discuss dignity and physical symptoms to a lesser extent.<sup>31</sup>

## Framing Effects

Views on the importance of MAID restrictions differed substantially within the Questionnaire and Vignette arms, particularly in terms of age, waiting period, and residency, and to a lesser extent in terms of a psychiatric or palliative care consultation. This aligns with existing evidence that suggests that attitudes towards the practice of MAID are significantly impacted by framing effects, in that the way a question is presented and/or phrased can shift the degree of support for or against the topic in question.<sup>11,15,32</sup> While we are unaware of any other studies that examined how framing effects might affect support for the practice of or restrictions related to MAID, and while the survey instruments in this study were not parallel enough to perform statistical significance testing, the

results of this survey might suggest that more personal narratives might garner more support for the practice and less concern with restrictions than abstract questionnaire items. This aligns with research in moral psychology that has demonstrated how intuitions related to moral responsibility tend to increase when more affective narratives are presented,<sup>33</sup> suggesting that other moral judgments, such as those related to the permissibility of MAID, may also be altered by the degree of abstraction.

## Limitations

The results of this survey are significantly limited by the small sample size, as well as the lack of diversity among the health care professionals that took the survey. Future studies should focus on obtaining a substantially larger scale and more diverse investigation of attitudes towards MAID.

## Conclusion

As a formal investigation of the attitudes of NYS-specific health care professionals towards MAID has not been conducted since the late 1990s, the results from this study offer up-to-date information to help inform both current New York State legislation, and the discussion on the ethical permissibility of MAID in general. Support for MAID in NYS has grown substantially over the last two decades, and more nation-wide data with a specific focus on the various restrictions and safeguards that must be built in to ensure safe and controlled use of the practice will be crucial as more states consider legalizing MAID.

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## List of Abbreviations

MAID = Medical Aid in Dying

NYS = New York State

## Declarations

### • Ethics approval and consent to participate

- Written consent was obtained for this study, but the study did not involve human subjects research as it did not collect personally identifiable information. **Please see “Additional Documents” for the consent form.**

- The study was approved by the New York University School of Medicine Institutional Review Board (Study ID i17-00264).

### • Consent for publication

- Not applicable

### • Availability of data and material

- The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

### • Competing interests

- The authors declare that they have no competing interests

### • Funding

- Funding to purchase access to a clearinghouse with registered health care professional's emails was provided by the New York University Department of Population Health, Division of Medical Ethics.

### • Authors' contributions

- All authors have read the manuscript and approved it for submission.



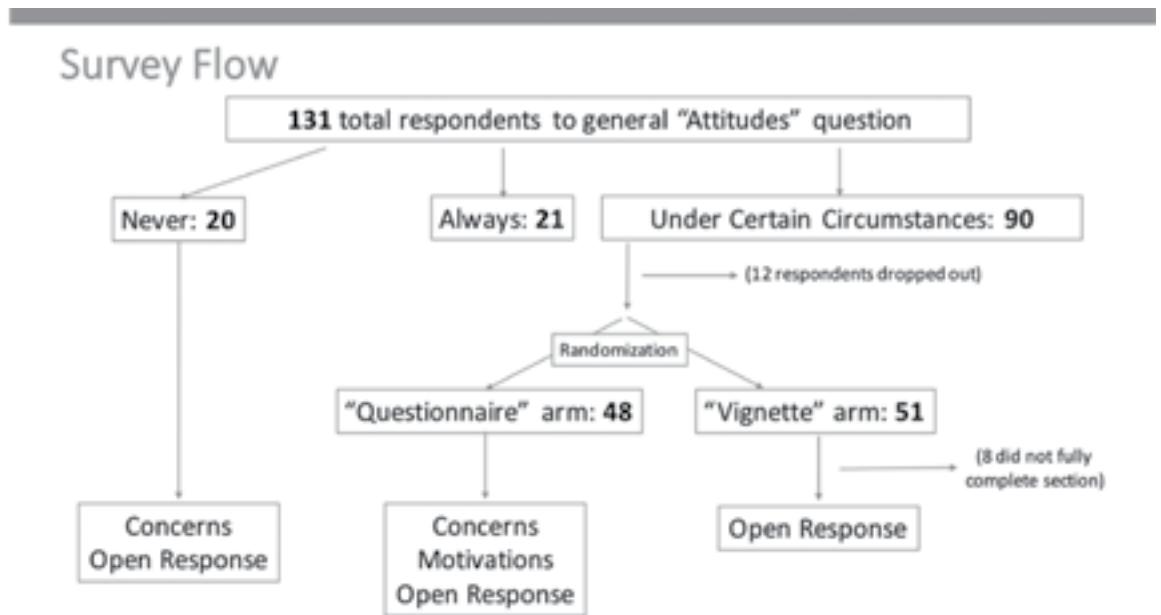
- **JS:**
  - Corresponding author
  - Made substantial contributions to survey conception and design
  - Made substantial contributions to or acquisition of data
  - Involved in drafting the manuscript or revising it critically for important intellectual content
- **PF:**
  - Made substantial contributions to or acquisition of data
  - Involved in drafting the manuscript or revising it critically for important intellectual content
  - Agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved
- **AK:**
  - Made substantial contributions to analysis and interpretation of data and relevant writing
- **BP:**
  - Agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved
  - Involved in drafting the manuscript or revising it critically for important intellectual content
  - Made substantial contributions to or acquisition of data
  - Gave final approval of the version to be published
- **Acknowledgements**
  - None
- **Authors information**
  - **JS:** Resident Physician, University of Miami Miller School of Medicine/Jackson Memorial Hospital, jonathan.steinberg@jhsmiami.org
  - **PF:** Biomedical Ethics Unit, Department of Social Studies of Medicine, McGill University, phoebe.friesen@mcgill.ca
  - **AK:** Associate Professor of Psychology, Saint Michael's College, akirshenbaum@smcvt.edu
  - **BP:** Assistant Professor, Division of Medical Ethics, NYU School of Medicine, brendan.parent@nyu.eduables, Figures, Additional Files

**Table 1:** Participant demographics (n = 131)

Variable	n (%)	
Age	18-29	8 (6.1)
	30-39	15 (11.5)
	40-49	30 (22.9)
	50-59	34 (26.0)
	60-69	23 (17.6)
	70-79	17 (13.0)
	80 or older	4 (3.1)
Gender	Male	45 (34.4)
	Female	86 (65.6)
Ethnicity	White	104 (78.8)
	Asian Ethnicities	15 (11.3)
	African American/Black	8 (6.1)
	Hispanic	5 (3.8)
Religion	Christian sects	47 (36.4)
	Judaism	39 (30.2)
	Other	10 (7.6)
	None	33 (25.6)
Attendance at religious services	> Monthly	30 (25.6)
	≥Yearly but < Monthly	33 (28.2)
	< Yearly	17 (14.5)
	Never	37 (31.6)
Profession	Physician	60 (49.5)
	Nurse	45 (37.1)
	Social Worker	16 (13.2)
Specialty	End-of-life specific specialties (Palliative Care, Geriatrics, Oncology, Hospice)	29 (22.8)
	Other specialties	98 (77.2)
Practice Setting	Hospital	70 (57.9)
	Office/Private Practice	33 (27.3)
	Nursing Facilities/Hospice/Home	18 (14.9)
Years in Practice	1-10	33 (25.2)
	11-20	33 (25.2)
	21-30	30 (22.9)
	More than 30	35 (26.7)

**Figure 1: Survey Flow**

Illustration of the survey flow, the number of participants who completed each section, and the number of participants randomized into each study arm.



**Figure 2: Importance of Concerns**

Importance of concerns for those who believe MAID is: (a) "Never" permissible, and (b) permissible "Under Some Circumstances" or "Always."



# Assembly Bill A4321A: Medical Aid in Dying

MAID

EXPLANATION—Matter in italics (underscored) is new; matter in brackets [ ] is old law to be omitted.

STATE OF NEW YORK

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4321

2021-2022 Regular Sessions

IN ASSEMBLY

February 1, 2021

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Introduced by M. of A. PAULIN, L. ROSENTHAL, GOTTFRIED, DINOWITZ, GALEF, HEVESI, STECK, LAVINE, LUPARDO, ABINANTI, RODRIGUEZ, VANEL, QUART, J. RIVERA, M. MILLER, THIELE, EPSTEIN, SEAWRIGHT, WOERNER, REYES, FRONTUS, FERNANDEZ, FALL, DARLING, CRUZ, SAYEGH, PICHARDO, AUBRY, DAVILA, DICKENS, STERN, BURDICK, GALLAGHER, FORREST, KELLES, GONZALEZ-ROJAS – Multi-Sponsored by – M. of A. BRAUNSTEIN, CARROLL, ENGLEBRIGHT, RAMOS – read once and referred to the Committee on Health

AN ACT to amend the public health law, in relation to a terminally ill patient's request for and use of medication for medical aid in dying

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

**Section 1. This act shall be known and may be cited as the "medical aid in dying act."**

**§ 2. The public health law is amended by adding a new article 28-F to read as follows:**

ARTICLE 28-F

MEDICAL AID IN DYING

Section 2899-d. Definitions.

2899-e. Request process.

2899-f. Attending physician responsibilities.

2899-g. Right to rescind request; requirement to offer opportunity to rescind.

2899-h. Consulting physician responsibilities.

2899-i. Referral to mental health professional.

2899-j. Medical record documentation requirements.

2899-k. Form of written request and witness attestation.

2899-l. Protection and immunities.

2899-m. Permissible refusals and prohibitions.

2899-n. Relation to other laws and contracts.

2899-o. Safe disposal of unused medications.

2899-p. Death certificate.

2899-q. Reporting.

2899-r. Penalties.

2899-s. Severability.

**§ 2899-d. Definitions. As used in this article:**

1. "Adult" means an individual who is eighteen years of age or older.
2. "Attending physician" means the physician who has primary responsibility for the care of the patient and treatment of the patient's terminal illness or condition.
3. "Capacity" means the ability to understand and appreciate the nature and consequences of health care decisions, including the benefits and risks of and alternatives to any proposed health care, including medical aid in dying, and to reach an informed decision.
4. "Consulting physician" means a physician who is qualified by specialty or experience to make a professional diagnosis and prognosis regarding a person's terminal illness or condition.
5. "Health care facility" means a general hospital, nursing home, or residential health care facility as defined in section twenty-eight hundred one of this chapter, or a hospice as defined in section four thousand two of this chapter; provided that for the purposes of section twenty eight hundred ninety-nine-m of this article, "hospice" shall refer only to a facility providing in-patient hospice care or a hospice residence.
6. "Health care provider" means a person licensed, certified, or authorized by law to administer health care or dispense medication in the ordinary course of business or practice of a profession.
7. "Informed decision" means a decision by a patient who is suffering from a terminal illness or condition to request and obtain a prescription for medication that the patient may self-administer to end the patient's life that is based on an understanding and acknowledgment of the relevant facts and that is made voluntarily, of the patient's own volition and without coercion, after being fully informed of:
  - (a) the patient's medical diagnosis and prognosis;
  - (b) the potential risks associated with taking the medication to be prescribed;
  - (c) the probable result of taking the medication to be prescribed;
  - (d) the possibility that the patient may choose not to obtain the medication, or may obtain the medication but may decide not to self-administer it; and
  - (e) the feasible alternatives and appropriate treatment options, including but not limited to palliative care and hospice care.
8. "Medical aid in dying" means the medical practice of a physician prescribing medication to a qualified individual that the individual may choose to self-administer to bring about death.

9. "Medically confirmed" means the medical opinion of the attending physician that a patient has a terminal illness or condition and has made an informed decision which has been confirmed by a consulting physician who has examined the patient and the patient's relevant medical records.
10. "Medication" means medication prescribed by a physician under this article.
11. "Mental health professional" means a licensed physician, who is a diplomate or eligible to be certified by a national board of psychiatry, psychiatric nurse practitioner, or psychologist, licensed or certified under the education law acting within his or her scope of practice and who is qualified, by training and experience, certification, or board certification or eligibility, to make a determination under section twenty-eight hundred ninety-nine-i of this article.
12. "Palliative care" means health care treatment, including interdisciplinary end-of-life care, and consultation with patients and family members, to prevent or relieve pain and suffering and to enhance the patient's quality of life, including hospice care under article forty of this chapter.
13. "Patient" means a person who is eighteen years of age or older under the care of a physician.
14. "Physician" means an individual licensed to practice medicine in New York state.
15. "Qualified individual" means a patient with a terminal illness or condition, who has capacity, has made an informed decision, and has satisfied the requirements of this article in order to obtain a prescription for medication.
16. "Self-administer" means a qualified individual's affirmative, conscious, and voluntary act of using medication under this article.
17. "Terminal illness or condition" means an incurable and irreversible illness or condition that has been medically confirmed and will, within reasonable medical judgment, produce death within six months.

**§ 2899-e. Request process.**

1. Oral and written request. A patient wishing to request medication under this article shall make an oral request and submit a written request to the patient's attending physician.
2. Making a written request. A patient may make a written request for and consent to self-administer medication for the purpose of ending his or her life in accordance with this article if the patient:
  - (a) has been determined by the attending physician to have a terminal illness or condition and which has been medically confirmed by a consulting physician; and
  - (b) based on an informed decision, expresses voluntarily, of the patient's own volition and without coercion the request for medication to end his or her life.
3. Written request signed and witnessed.
  - (a) A written request for medication under this article shall be signed and dated by the patient and witnessed by at least two adults who, in the presence of the patient, attest that to the best of his or her knowledge and belief the patient has capacity, is acting voluntarily, is making the request for medication of his or her own volition and is not being coerced to sign the request. The written request shall be in substantially the form described in section twenty-eight hundred ninety-nine-k of this article.
  - (b) One of the witnesses shall be an adult who is not:
    - (i) a relative of the patient by blood, marriage or adoption;
    - (ii) a person who at the time the request is signed would be entitled to any portion of the estate of the patient upon death under any will or by operation of law; or
    - (iii) an owner, operator, employee or independent contractor of a health care facility where the patient is receiving treatment or is a resident.
  - (c) The attending physician, consulting physician and, if applicable, the mental health professional who provides a capacity determination of the patient under this article shall not be a witness.
4. No person shall qualify for medical aid in dying under this article solely because of age or disability.

5. Requests for a medical aid-in-dying prescription must be made by the qualified individual and may not be made by any other individual, including the qualified individual's health care agent, or other agent or surrogate, or via advance healthcare directive.

**§ 2899-f. Attending physician responsibilities.**

1. The attending physician shall examine the patient and his or her relevant medical records and:
  - (a) make a determination of whether a patient has a terminal illness or condition, has capacity, has made an informed decision and has made the request voluntarily of the patient's own volition and without coercion;
  - (b) inform the patient of the requirement under this article for confirmation by a consulting physician, and refer the patient to a consulting physician upon the patient's request;
  - (c) refer the patient to a mental health professional pursuant to section twenty-eight hundred ninety-nine-i of this article if the attending physician believes that the patient may lack capacity to make an informed decision;
  - (d) provide information and counseling under section twenty-nine hundred ninety-seven-c of this chapter;
  - (e) ensure that the patient is making an informed decision by discussing with the patient:
    - (i) the patient's medical diagnosis and prognosis;
    - (ii) the potential risks associated with taking the medication to be prescribed;
    - (iii) the probable result of taking the medication to be prescribed;
    - (iv) the possibility that the patient may choose to obtain the medication but not take it;
    - (v) the feasible alternatives and appropriate treatment options, including but not limited to
      - (1) information and counseling regarding palliative and hospice care and end-of-life options appropriate to the patient, including but not limited to: the range of options appropriate to the patient; the prognosis, risks and benefits of the various options; and the patient's legal rights to comprehensive pain and symptom management at the end of life; and
      - (2) information regarding treatment options appropriate to the patient, including the prognosis, risks and benefits of the various treatment options;
  - (f) offer to refer the patient for other appropriate treatment options, including but not limited to palliative care and hospice care;
  - (g) discuss with the patient the importance of:
    - (i) having another person present when the patient takes the medication and the restriction that no person other than the patient may administer the medication;
    - (ii) not taking the medication in a public place; and
    - (iii) informing the patient's family of the patient's decision to request and take medication that will end the patient's life; a patient who declines or is unable to notify family shall not have his or her request for medication denied for that reason;
  - (h) inform the patient that he or she may rescind the request for medication at any time and in any manner;
  - (i) fulfill the medical record documentation requirements of section twenty-eight hundred ninety-nine-j of this article; and
  - (j) ensure that all appropriate steps are carried out in accordance with this article before writing a prescription for medication.
2. Upon receiving confirmation from a consulting physician under section twenty-eight hundred ninety-nine-h of this article and subject to section twenty-eight hundred ninety-nine-i of this article, the attending physician who determines that the patient has a terminal illness or condition, has capacity and has made a voluntary request for medication as provided in this article, may personally, or by referral to another physician, prescribe or order appropriate medication in accordance with the patient's request under this article, and at the patient's request, facilitate the filling of the prescription and delivery of the medication to the patient.

3. In accordance with the direction of the prescribing or ordering physician and the consent of the patient, the patient may self-administer the medication to himself or herself. A health care professional or other person shall not administer the medication to the patient.

**§ 2899-g. Right to rescind request; requirement to offer opportunity to rescind.**

1. A patient may at any time rescind his or her request for medication under this article without regard to the patient's capacity.
2. A prescription for medication may not be written without the attending physician offering the qualified individual an opportunity to rescind the request.

**§ 2899-h. Consulting physician responsibilities.** Before a patient who is requesting medication may receive a prescription for medication under this article, a consulting physician must:

1. examine the patient and his or her relevant medical records;
2. confirm, in writing, to the attending physician and the patient, whether:
  - (a) the patient has a terminal illness or condition;
  - (b) the patient is making an informed decision;
  - (c) the patient has capacity, or provide documentation that the consulting physician has referred the patient for a determination under section twenty-eight hundred ninety-nine-i of this article; and
  - (d) the patient is acting voluntarily, of the patient's own volition and without coercion.

**§ 2899-i. Referral to mental health professional.**

1. If the attending physician or the consulting physician determines that the patient may lack capacity to make an informed decision due to a condition, including, but not limited to, a psychiatric or psychological disorder, or other condition causing impaired judgement, the attending physician or consulting physician shall refer the patient to a mental health professional for a determination of whether the patient has capacity to make an informed decision. The referring physician shall advise the patient that the report of the mental health professional will be provided to the attending physician and the consulting physician.
2. A mental health professional who evaluates a patient under this section shall report, in writing, to the attending physician and the consulting physician, his or her independent conclusions about whether the patient has capacity to make an informed decision, provided that if, at the time of the report, the patient has not yet been referred to a consulting physician, then upon referral the attending physician shall provide the consulting physician with a copy of the mental health professional's report. If the mental health professional determines that the patient lacks capacity to make an informed decision, the patient shall not be deemed a qualified individual, and the attending physician shall not prescribe medication to the patient.
3. A determination made pursuant to this section that an adult patient lacks decision-making capacity shall not be construed as a finding that the patient lacks capacity for any other purpose.

**§ 2899-j. Medical record documentation requirements.** An attending physician shall document or file the following in the patient's medical record:

1. the dates of all oral requests by the patient for medication under this article;
2. the written request by the patient for medication under this article, including the declaration of witnesses and interpreter's declaration, if applicable;
3. the attending physician's diagnosis and prognosis, determination of capacity, and determination that the patient is acting voluntarily, of the patient's own volition and without coercion, and has made an informed decision;
4. if applicable, written confirmation of capacity under section twenty-eight hundred ninety-nine-i of this article; and
5. a note by the attending physician indicating that all requirements under this article have been met and indicating the steps taken to carry out the request, including a notation of the medication prescribed or ordered.

**§ 2899-k. Form of written request and witness attestation.**

1. A request for medication under this article shall be in substantially the following form:

**REQUEST FOR MEDICATION TO END MY LIFE**

I, \_\_\_\_\_, am an adult who has capacity, which means I understand and appreciate the nature and consequences of health care decisions, including the benefits and risks of and alternatives to any proposed health care, and to reach an informed decision and to communicate health care decisions to a physician. I have been diagnosed with \_\_\_\_\_ (insert diagnosis), which my attending physician has determined is a terminal illness or condition, which has been medically confirmed by a consulting physician. I have been fully informed of my diagnosis and prognosis, the nature of the medication to be prescribed and potential associated risks, the expected result, and the feasible alternatives and treatment options including but not limited to palliative care and hospice care. I request that my attending physician prescribe medication that will end my life if I choose to take it, and I authorize my attending physician to contact another physician or any pharmacist about my request.

INITIAL ONE:

( ) I have informed or intend to inform one or more members of my family of my decision.

( ) I have decided not to inform any member of my family of my decision.

( ) I have no family to inform of my decision.

I understand that I have the right to rescind this request or decline to use the medication at any time.

I understand the importance of this request, and I expect to die if I take the medication to be prescribed.

I further understand that although most deaths occur within three hours, my death may take longer, and my attending physician has counseled me about this possibility.

I make this request voluntarily, of my own volition and without being coerced, and I accept full responsibility for my actions.

Signed: \_\_\_\_\_

Dated: \_\_\_\_\_

**DECLARATION OF WITNESSES**

I declare that the person signing this "Request for Medication to End My Life":

- (a) is personally known to me or has provided proof of identity;
- (b) voluntarily signed the "Request for Medication to End My Life" in my presence or acknowledged to me that he or she signed it; and
- (c) to the best of my knowledge and belief, has capacity and is making the "Request for Medication to End My Life" voluntarily, of his or her own volition and is not being coerced to sign the "Request for Medication to End My Life".

I am not the attending physician or consulting physician of the person signing the "Request for Medication to End My Life" or, if applicable, the mental health professional who provides a capacity determination of the person signing the "Request for Medication to End My Life" at the time the "Request for Medication to End My Life" was signed.

I further declare under penalty of perjury that the statements made herein are true and correct and false statements made herein are punishable.

\_\_\_\_\_ Witness 1, Date: \_\_\_\_\_

\_\_\_\_\_ (Printed name)

\_\_\_\_\_ (Address)

\_\_\_\_\_ (Telephone number)

I further declare that I am not (i) related to the above-named patient by blood, marriage or adoption, (ii) entitled at the time the patient signed the "Request for Medication to End My Life" to any portion of the estate of the patient upon



his/her death under any will or by operation of law, or (iii) an owner, operator, employee or independent contractor of a health care facility where the patient is receiving treatment or is a resident.

\_\_\_\_\_ Witness 2, Date: \_\_\_\_\_

\_\_\_\_\_ (Printed name)

\_\_\_\_\_ (Address)

\_\_\_\_\_ (Telephone number)

NOTE: Only one of the two witnesses may

- (i) be a relative (by blood, marriage or adoption) of the person signing the "Request for Medication to End My Life",
  - (ii) be entitled to any portion of the person's estate upon death under any will or by operation of law, or
  - (iii) own, operate, be employed or be an independent contractor at a health care facility where the person is receiving treatment or is a resident.
2. (a) The "Request for Medication to End My Life" shall be written in the same language as any conversations, consultations, or interpreted conversations or consultations between a patient and at least one of his or her attending or consulting physicians.

(b) Notwithstanding paragraph (a) of this subdivision, the written "Request for Medication to End My Life" may be prepared in English even when the conversations or consultations or interpreted conversations or consultations were conducted in a language other than English or with auxiliary aids or hearing, speech or visual aids, if the English language form includes an attached declaration by the interpreter of the conversation or consultation, which shall be in substantially the following form:

#### **INTERPRETER'S DECLARATION**

I, \_\_\_\_\_ (insert name of interpreter) \_\_\_\_\_, (mark as applicable):

( ) for a patient whose conversations or consultations or interpreted conversations or consultations were conducted in a language other than English and the "Request for Medication to End My Life" is in English: I declare that I am fluent in English and (insert target language). I have the requisite language and interpreter skills to be able to interpret effectively, accurately and impartially information shared and communications between the attending or consulting physician and (name of patient).

I certify that on (insert date), at approximately (insert time), I interpreted the communications and information conveyed between the physician and (name of patient) as accurately and completely to the best of my knowledge and ability and read the "Request for Medication to End My Life" to (name of patient) in (insert target language).

(Name of patient) affirmed to me his/her desire to sign the "Request for Medication to End My Life" voluntarily, of (name of patient)'s own volition and without coercion.

( ) for a patient with a speech, hearing or vision disability: I declare that I have the requisite language, reading and/or interpreter skills to communicate with the patient and to be able to read and/or interpret effectively, accurately and impartially information shared and communications that occurred on (insert date) between the attending or consulting physician and (name of patient).

I certify that on (insert date), at approximately (insert time), I read and/or interpreted the communications and information conveyed between the physician and (name of patient) impartially and as accurately and completely to the best of my knowledge and ability and, where needed for effective communication, read or interpreted the "Request for Medication to End my Life" to (name of patient).

(Name of patient) affirmed to me his/her desire to sign the "Request for Medication to End My Life" voluntarily, of (name of patient)'s own volition and without coercion.

I further declare under penalty of perjury that (i) the foregoing is true and correct; (ii) I am not (A) related to (name of patient) by blood, marriage or adoption, (B) entitled at the time (name of patient) signed the "Request for Medication to End My Life" to any portion of the estate of (name of patient) upon his/her death under any will or by operation

of law, or (C) an owner, operator, employee or independent contractor of a health care facility where (name of patient) is receiving treatment or is a resident, except that if I am an employee or independent contractor at such health care facility, providing interpreter services is part of my job description at such health care facility or I have been trained to provide interpreter services and (name of patient) requested that I provide interpreter services to him/her for the purposes stated in this Declaration; and (iii) false statements made herein are punishable.

Executed at (insert city, county and state) on this (insert day of month) of (insert month), (insert year).

\_\_\_\_\_ (Signature of Interpreter)

\_\_\_\_\_ (Printed name of Interpreter)

\_\_\_\_\_ (ID # or Agency Name)

\_\_\_\_\_ (Address of Interpreter)

\_\_\_\_\_ (Language Spoken by Interpreter)

- (c) An interpreter whose services are provided under paragraph (b) of this subdivision shall not
- (i) be related to the patient who signs the "Request for Medication to End My Life" by blood, marriage or adoption,
  - (ii) be entitled at the time the "Request for Medication to End My Life" is signed by the patient to any portion of the estate of the patient upon death under any will or by operation of law, or
  - (iii) be an owner, operator, employee or independent contractor of a health care facility where the patient is receiving treatment or is a resident; provided that an employee or independent contractor whose job description at the health care facility includes interpreter services or who is trained to provide interpreter services and who has been requested by the patient to serve as an interpreter under this article shall not be prohibited from serving as a witness under this article.

**§ 2899-l. Protection and immunities.**

1. A physician, pharmacist, other health care professional or other person shall not be subject to civil or criminal liability or professional disciplinary action by any government entity for taking any reasonable good-faith action or refusing to act under this article, including, but not limited to:
  - (a) engaging in discussions with a patient relating to the risks and benefits of end-of-life options in the circumstances described in this article,
  - (b) providing a patient, upon request, with a referral to another health care provider,
  - (c) being present when a qualified individual self-administers medication,
  - (d) refraining from acting to prevent the qualified individual from self-administering such medication, or
  - (e) refraining from acting to resuscitate the qualified individual after he or she self-administers such medication.
2. Nothing in this section shall limit civil or criminal liability for negligence, recklessness or intentional misconduct.

**§ 2899-m. Permissible refusals and prohibitions.**

1. (a) A physician, nurse, pharmacist, other health care provider or other person shall not be under any duty, by law or contract, to participate in the provision of medication to a patient under this article.

(b) If a health care provider is unable or unwilling to participate in the provision of medication to a patient under this article and the patient transfers care to a new health care provider, the prior health care provider shall transfer or arrange for the transfer, upon request, of a copy of the patient's relevant medical records to the new health care provider.

2. (a) A private health care facility may prohibit the prescribing, dispensing, ordering or self-administering of medication under this article while the patient is being treated in or while the patient is residing in the health care facility if:
  - (i) the prescribing, dispensing, ordering or self-administering is contrary to a formally adopted policy of the facility that is expressly based on sincerely held religious beliefs or moral convictions central to the facility's operating principles; and
  - (ii) the facility has informed the patient of such policy prior to admission or as soon as reasonably possible.

(b) Where a facility has adopted a prohibition under this subdivision, if a patient who wishes to use medication under this article requests, the patient shall be transferred promptly to another health care facility that is reasonably accessible under the circumstances and willing to permit the prescribing, dispensing, ordering and self-administering of medication under this article with respect to the patient.

3. Where a health care facility has adopted a prohibition under this subdivision, any health care provider or employee or independent contractor of the facility who violates the prohibition may be subject to sanctions otherwise available to the facility, provided the facility has previously notified the health care provider, employee or independent contractor of the prohibition in writing.

#### **§ 2899-n. Relation to other laws and contracts.**

1. (a) A patient who requests medication under this article shall not, because of that request, be considered to be a person who is suicidal, and self-administering medication under this article shall not be deemed to be suicide, for any purpose.

(b) Action taken in accordance with this article shall not be construed for any purpose to constitute suicide, assisted suicide, attempted suicide, promoting a suicide attempt, euthanasia, mercy killing, or homicide under the law, including as an accomplice or accessory or otherwise.
2. (a) No provision in a contract, will or other agreement, whether written or oral, to the extent the provision would affect whether a person may make or rescind a request for medication or take any other action under this article, shall be valid.

(b) No obligation owing under any contract shall be conditioned or affected by the making or rescinding of a request by a person for medication or taking any other action under this article.
3. (a) A person and his or her beneficiaries shall not be denied benefits under a life insurance policy for actions taken in accordance with this article.

(b) Notwithstanding the provisions of any law or contract, the sale, procurement or issuance of a life or health insurance or annuity policy, or the rate charged for a policy, shall not be conditioned upon or affected by a patient making or rescinding a request for medication under this article.
4. An insurer shall not provide any information in communications made to a patient about the availability of medication under this article absent a request by the patient or by his or her attending physician upon the request of such patient. Any communication shall not include both the denial of coverage for treatment and information as to the availability of medication under this article.
5. The sale, procurement, or issue of any professional malpractice insurance policy or the rate charged for the policy shall not be conditioned upon or affected by whether the insured does or does not take or participate in any action under this article.

#### **§ 2899-o. Safe disposal of unused medications.**

A person who has custody or control of any unused medication prescribed under this article after the death of the qualified individual shall personally deliver the unused medication for disposal to the nearest qualified facility that properly disposes of controlled substances or shall dispose of it by lawful means in accordance with regulations made by the commissioner, regulations made by or guidelines of the commissioner of education, or guidelines of a federal drug enforce-

ment administration approved take-back program. A qualified facility that properly disposes of controlled substances shall accept and dispose of any medication delivered to it as provided hereunder regardless of whether such medication is a controlled substance. The commissioner may make regulations as may be appropriate for the safe disposal of unused medications prescribed, dispensed or ordered under this article as provided in this section.

**§ 2899-p. Death certificate.**

1. If otherwise authorized by law, the attending physician may sign the qualified individual's death certificate.
2. The cause of death listed on a qualified individual's death certificate who dies after self-administering medication under this article will be the underlying terminal illness or condition.

**§ 2899-q. Reporting.**

1. The commissioner shall annually review a sample of the records maintained under sections twenty-eight hundred ninety-nine-j and twenty-eight hundred ninety-nine-p of this article. The commissioner shall adopt regulations establishing reporting requirements for physicians taking action under this article to determine utilization and compliance with this article. The information collected under this subdivision shall not constitute a public record available for public inspection and shall be confidential and collected and maintained in a manner that protects the privacy of the patient, his or her family, and any health care provider acting in connection with such patient under this article, except that such information may be disclosed to a governmental agency as authorized or required by law relating to professional discipline, protection of public health or law enforcement.
2. The commissioner shall prepare a report annually containing relevant data regarding utilization and compliance with this article and shall send such report to the legislature, and post such report on the department's website.

**§ 2899-r. Penalties.**

1. Nothing in this article shall be construed to limit professional discipline or civil liability resulting from conduct in violation of this article, negligent conduct, or intentional misconduct by any person.
2. Conduct in violation of this article shall be subject to applicable criminal liability under state law, including, where appropriate and without limitation, offenses constituting homicide, forgery, coercion, and related offenses, or federal law.

**§ 2899-s. Severability.**

If any provision of this article or any application of any provision of this article, is held to be invalid, or to violate or be inconsistent with any federal law or regulation, that shall not affect the validity or effectiveness of any other provision of this article, or of any other application of any provision of this article, which can be given effect without that provision or application; and to that end, the provisions and applications of this article are severable.

**§ 3. This act shall take effect immediately.**

# Qui Tam Quarterly: COVID-19 and the Big-Data Revolution of Health Care False Claims Act Litigation

By Stephen D. Bittinger, Mark A. Rush, Nora E. Becerra and Kristina M. DiPano

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The regulatory scheme governing the submission and payment of claims for health care services to government payers is complex and convoluted. It is a slippery slope for the unaware or ill informed. The health care claims system is predicated on the concept that the government pays submitted claims without review or comment and thereafter seeks to recover improper payments—including through the potential application of penalties and damages—if providers do not adhere to the relevant regulations. That system became exponentially more complex as a result of COVID-19, which created a staggering number of regulatory changes to the system since March 2020.

In 2019, even without these dramatic changes, Medicare and Medicaid accounted for \$103.6 billion of improper payments, and the Department of Justice (DOJ) recovered \$2.6 billion of improper health care payments on the basis of asserted False Claims Act (FCA) liability. As a result, the government and relators have turned to a new and growing tool to investigate and pursue health care FCA actions: statistical sampling and extrapolation of mass claims data. The industry has recently seen the results of the government's use of this tool in Operation Brace Yourself, Operation Double Helix, and the massive \$6 billion Health Care Fraud Takedown announced in September 2020.

The tidal wave of reimbursement-related regulatory change brought on by COVID-19 will force relators and the DOJ to rely on big-data analysis in FCA litigation in an unprecedented manner. The Office of Inspector General (OIG) for the U.S. Department of Health and Human Services (HHS) has already reported to Congress an anticipated \$4 billion in expected recoveries for FY2020 with \$942 million based on audit findings and more than \$3.14 billion based on investigation recoveries, which includes 791 civil actions for false claims and unjust-enrichment.<sup>1</sup> In addition, the Office of the General Counsel for HHS just announced the formation of a FCA Working Group comprised of former FCA and health care fraud prosecutors, former private counsel for health care and life science companies, and HHS attorneys to investigate the more than \$1.5 trillion in grants and payments disbursed in 2020.<sup>2</sup>

This edition of Qui Tam Quarterly focuses on:

- the history of big data in health care FCA investigations and litigation;
- how the government has increased its ability to gather health care claims data and use it to support FCA allegations;
- how big data will most likely be used as a primary tool for investigations to evaluate potential fraud due to regulatory changes brought on by COVID-19; and
- how providers can use big claims data to control discovery costs in investigations and to better understand the operations of their compliance programs to prevent improper claims from being filed.

This edition concludes with key strategies for defending allegations supported by extrapolated overpayments and some best practices for using claims data to proactively defend against scrutiny. Specifically, information and recommendations are provided on how to undermine the validity of findings on a sample set of claims that can be

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**Stephen D. Bittinger is a partner with K&L Gates in the firm's Washington, DC and Charleston office. He is a member of the health care/FDA practice group. He focuses his practice on health care reimbursement compliance, defense and litigation, with a focus on government and private payer disputes on behalf of providers, vendors, and suppliers involved in the United States health care system.**

**Mark A. Rush is a partner with K&L Gates and concentrates his practice on litigation as a trial lawyer, with emphasis on internal investigations, corporate criminal defense, Bank Secrecy Act and AML issues, False Claims Act defense and complex commercial litigation.**

**Nora E. Becerra is an associate with K&L Gates in the Chicago office and represents healthcare clients in regulatory and litigation matters, including responding to governmental investigations and defending False Claims Act lawsuits.**

**Kristina M. DiPano is an associate with K&L Gates in the firm's Charleston office. She is a member of the health care/FDA practice group.**

used to invalidate the extrapolated assumptions, how to effectively challenge an extrapolation based on improper sampling and auditing processes, and how to dispute the statistical extrapolation process after an extrapolated overpayment has been asserted against a provider. Finally, resources and suggestions are provided on how providers can take advantage of currently available claims data to reduce the risk of scrutiny.

## The Scope of Improper Health Care Payments and Origins of Proving They Were Fraudulent

To evaluate the potential improper payment of health care claims by government payers due to the regulatory changes brought on by the pandemic and the scope of FCA liability that may be asserted, it is appropriate to consider the results from the most current pre-pandemic year and how big data came to be used to support FCA liability during that period. In fiscal year 2019 alone, Medicare and Medicaid accounted for \$103.6 billion of improper payments made by the government, which was 59% of all government-wide estimated improper payments during this year.<sup>3</sup> Within that figure, Medicare fee-for-service accounted for \$28.9 billion with an error rate of 7.3%, Medicare Advantage plans attributed for \$16.7 billion with an error rate of 7.9%, and Medicaid was \$57.4 billion with an error rate of 14.9%.<sup>4</sup> While these figures include all error-based payments and potentially fraudulent claims paid, a comparison to the DOJ's results from last year is useful to consider how the rate of both may increase due to regulatory changes brought on by the pandemic. In 2019, the DOJ reported recovery of over \$3 billion from 782 FCA cases, \$2.6 billion (87%) of which was health care related.<sup>5</sup> As the vast majority of FCA health care cases rest on providers' submission of improper claims data, an understanding of how the government and relators use such vast amounts of information is warranted.

Statistical extrapolation, where findings on a sample set are presumed to accurately reflect the same result across a universe of claims, is one of the most powerful weapons of relators and the government in prosecuting health care FCA cases.

Although extrapolation may seem commonplace today, understanding the origin of its use and its limitations can make all the difference in defending the presumptions this weapon can raise. The solidification of statistical extrapolation as a credible means of proving a mass amount of health care claims were invalid or false without a claim-by-claim review gave birth to the use of big data to prove fraud in health care false claims litigation. In 1986, the Health Care Financing Administration (HCFA), the predecessor to the Centers for Medicare and Medicaid Services (CMS), ruled that a contract auditor was permitted to use sampling and extrapolation as opposed to a claim-by-claim review because:

- (a) the government has a significant interest in cost-effective recovery of improper payments;

- (b) even though there was no express authorization, there was also no express prohibition; and
- (c) providers were not denied due process because of their ability to appeal extrapolated findings through the administrative appeals process.<sup>6</sup> Before unpacking how extrapolation has evolved in FCA litigation, it is important to understand the government players and programs involved in gathering and producing the data that underlies the presumptions made by extrapolation.

Perhaps the most central in all health care fraud analysis throughout the U.S. health care system is the CMS Center for Program Integrity (CMS-CPI), a specific division of CMS that is the focal point of all national and statewide Medicare, Medicaid, and Children's Health Insurance Program integrity fraud and abuse issues.<sup>7</sup> CMS-CPI oversees all CMS interactions and collaborations with stakeholders relating to program integrity, including the DOJ, HHSOIG, state law-enforcement agencies, and other federal entities for the purpose of detecting, deterring, monitoring, and combating fraud and abuse, as well as taking action against those that commit or participate in fraud.<sup>8</sup> CMS-CPI is the heart of health care fraud investigation, and the claims data is the blood that it pumps through the Fraud Prevention System (FPS)—a complex software system that reads and analyzes the more than 1 billion claims processed per year.<sup>9</sup> However, access to CMS-CPI's data warehouse in the FPS is not limited to just federal payers.

In 2012, CMS-CPI began the Health Care Fraud Prevention Partnership with 20 public and private partners focused on data and information sharing, which has now grown to include 181 partners.<sup>10</sup> More recently, CMS-CPI began the Major Case Coordination program, which is a collaboration between CMS-CPI, HHS-OIG, and DOJ that led to large-scale takedowns like Operation Brace Yourself<sup>11</sup> and Operation Double Helix.<sup>12</sup> The collection, analysis, and dissemination of claims data was at the heart of these operations.<sup>13</sup> 2020 has proved to set new records in this arena, with the National Health Care Fraud Takedown in September<sup>14</sup> resulting in 345 defendants charged, including more than 100 medical professionals and an alleged fraud loss of more than \$6 billion, with the largest amount of the alleged loss—\$4.5 billion—involving telemedicine, the most changed method of delivery of services during the pandemic. Understanding how these multidistrict and national cases originate and evolve with the assistance of data analysis requires a look at how the law has changed in regard to the application of data in the FCA legal framework.

## Relators' Use of Big Data in Health Care FCA Cases

Government enforcement agencies have become increasingly well equipped to analyze and use big data to detect and prosecute fraud. In 2017, the DOJ Criminal



Division's Health Care Fraud Unit announced the launch of a "data analytics team" aimed at both identifying fraud and assisting with current prosecutions.<sup>15</sup> HHS-OIG also has encouraged state governments to use data mining to identify potential Medicaid fraud. CMS's Head Administrator Seema Verma stated that the organization was "moving to a system where we're able to take quality data from the EHR [electronic health record], we can combine it with claims data, we can see what's going on in program integrity . . . in a way, that's been fairly unprecedented."<sup>16</sup> The increased use of data analytics in fraud detection and prosecution is on the rise following the government's COVID-19 response, but it is not limited to government enforcement agencies alone.<sup>17</sup> Private relators have become key players in the FCA litigation landscape.<sup>18</sup> The COVID-19 crisis has set up a backdrop ripe with opportunity for private parties to recoup substantial monetary compensation by bringing FCA claims on the basis of data mining. According to the DOJ, of the approximately \$3 billion in FCA settlements filed in 2019, over \$2.1 billion arose from qui tam litigation, resulting in over \$265 million in payouts to individual relators.<sup>19</sup> Through tracking publicly available information, these private relators can detect abnormalities in claims data and pinpoint trends that fall outside of the normal deviations from the mean, thus equipping them with the building blocks of an FCA lawsuit. Moreover, the relaxation of many regulatory requirements, such as those in telemedicine, will likely lead providers to engage in more high-risk behavior and, in turn, cause good-faith billing/coding errors, inaccurate certifications and documentation, and other anomalous data to instead serve as indicators of FCA violations.

### Sampling and Presumptions

The mechanics of data analytics within the FCA context can be broken down into two generalized processes: statistical sampling and extrapolation. Statistical sampling is when random number generation is used to select a subset of a discrete population. Extrapolation is the second step of the process, where values are extended by inferring unknown values from trends in the known data in order to make determinations about the population as a whole. If done correctly, this is a highly effective way to predict patterns in data. If done incorrectly, it can manifest a warped representation of reality.

The technique of statistical sampling has been used to varying degrees of success by many relators. For example, in *United States v. Cabrera-Diaz*,<sup>20</sup> statistical sampling was used to establish FCA liability for claims submitted under Medicare. The issue of whether statistical extrapolation was appropriate came before the court when the defendant failed to appear and the government moved for a default judgment. While the court held that it was appropriate, the holding has been limited by the procedural posture of the case. For example, in *United States ex rel. Martin v. Life Care Centers of America, Inc.*,<sup>21</sup> the court noted that *Cabrera-Diaz* was limited in significance given that "[w]ithout evidence and argument opposing the government's position, the Court cannot view the result in *Cabrera-Diaz* as anything other than an unopposed remedy suggested by the government, which was granted through a procedural mechanism to obtain judgment from unresponsive parties."

In *United States ex rel. Loughren v. UnumProvident Corp.*,<sup>22</sup> statistical sampling was used to extrapolate the total number of false claims for the purpose of determining damages. However, this was allowed only after the court held a bellwether jury trial to determine whether sufficient evidence existed regarding defendant's pattern and practice of submitting false claims. Accordingly, despite supporting the use of extrapolation, *Loughren* can be limited to the robust mechanisms put into place by the court to evaluate intent. Other courts have allowed extrapolation only when claim-by-claim review is impracticable.<sup>23</sup> However, in *United States ex rel. Michaels v. Agape Senior Community, Inc.*,<sup>24</sup> the court reached the opposite conclusion.

In *Agape*, relators filed an FCA lawsuit against a network of nursing homes, alleging the nursing homes fraudulently submitted claims for services that were not medically necessary to Medicare, Medicaid, and TRI-CARE. The court described the case as involving a "staggering" number of claims. Relators retained two experts, and estimated that individualized review of all the claims at issue would cost between \$16 million and \$36.5 million. The court initially declined the use of statistical extrapolation at the discovery stage but later encouraged the parties to hold a bellwether trial involving a small sample of the allegedly false claims as a test to the veracity of the larger set of alleged false claims. Although the parties agreed to undergo the bellwether trial, they settled prior to its occurrence, to which the government objected and filed an interlocutory appeal. Following the appeal, the Fourth Circuit heard argument on

- (1) whether statistical sampling could be used to establish liability in a FCA case, and
- (2) whether the government could veto a FCA settlement in a case in which it had declined to intervene. The Fourth Circuit ruled that the government did possess the authority to veto a settlement in a non-intervened case, and refused to address whether sampling could be used to establish liability. This, once again, left an open question as to the viability of extrapolation as the basis for support in FCA cases.

Moreover, another point of contention across circuits is the application of the FCA's public disclosure bar, which prohibits relators from filing qui tam suits based on "substantially the same allegations or transactions" that were publicly disclosed in a government "report."<sup>25</sup> The Supreme Court has construed "report" broadly to include "something that gives information or a notification."<sup>26</sup> Accordingly, some lower courts have concluded that information published online by the government, including CMS claims data, can trigger the public disclosure bar. Before litigating the standards to be applied to sampling and extrapolation, a careful analysis should be performed of the process used by the auditor to support health care FCA claims.

## 1. Auditors' Role in Government-Initiated Health Care FCA Litigation

Although many litigators are aware that government audits are often involved in the origins of a FCA case, many may not be aware that the DOJ is directly collaborating with CMS contract auditors and that government-initiated FCA cases may originate from the referral of auditors. Unified Program Integrity Contractors (UPICs) have become the primary vehicle for CMS to investigate and data-mine for fraud in Medicare and Medicaid claims processing.<sup>27</sup> UPICs perform integrity work with Medicare Parts A and B, durable medical equipment, Home Health and Hospice, Medicaid, and the Medicare-Medicaid data match program.<sup>28</sup> The UPIC program was specifically created with the intent to consolidate all CMS integrity work to facilitate better coordination with the CMS-CPI, the Federal Bureau of Investigation (FBI), HHS-OIG, DOJ, and local law enforcement.<sup>29</sup>

UPIC regulations and guidance create an avenue to report suspected fraud to CMS-CPI, HHS-OIG, FBI, and DOJ.<sup>30</sup> UPICs gather data analysis leads that uncover inexplicable aberrancies that indicate potentially fraudulent, wasteful, or abusive billing for specific providers/suppliers.<sup>31</sup> UPICs also assist in ongoing investigations at the request of HHS or DOJ that involve national inter-agency initiatives or projects, cases with a likelihood of an increase in the amount of fraud or enlargement of a pattern, multi-state fraud, and high-dollar amounts of potential overpayments or other administrative actions (e.g., payment suspensions and revocations).<sup>32</sup> UPICs and their employees and professional consultants are protected from criminal and civil liability as long as their duties were performed with due care in the course of their contract.<sup>33</sup> UPICs are required to maintain all their work in the Unified Case Management (UCM) system.<sup>34</sup>

The UCM is a national database that UPICs use to enter Medicare and Medicaid fraud, waste, and abuse data analysis projects, leads, and investigations initiated by UPICs.<sup>35</sup> UPICs use the UCM to track administrative actions, requests for assistance, and requests for information from law enforcement. The UCM is currently accessible by UPICs, the National Benefit Integrity Medicare Drug Integrity Contractor, the Railroad Retirement Board, CMS contractors (FPS, PIMAS, Acumen, IBM), Medicare Administrative Contractors (MAC), Medical Review Units associated with MPIP, CMS, FBI, DOJ, HHS-OIG, and other federal and state partners seeking to address program integrity concerns in judicial or state health care programs.<sup>36</sup> The UCM is a live-feed from UPIC auditors to the DOJ, and the DOJ has become increasingly effective in using this big-data tool to investigate and prosecute civil and criminal FCA cases on national cases.

In a 20 November 2020 press release by the DOJ, the U.S. Attorney's Office for the District of Minnesota highlighted a FCA case initiated by the government against two medical laboratories, their owner, and an employee.<sup>37</sup>



Although the settlement amount of US \$500,000 based on ability to pay and exclusions are not of significant note, it is of interest that this settlement was based on the government's own case against the defendants for their role in "knowingly causing" other providers to submit false claims for medically unnecessary services. The release goes on to highlight that this upstream liability asserted against the defendants was based on "a proactive government investigation based on a critical analysis of Medicare claims data." Lamont Pugh, III, Special Agent in Charge for HHS-OIG, Chicago Region, was quoted as stating, "The OIG routinely conducts data analysis in an effort to identify aberrant and potentially fraudulent billing trends and will take action to hold accountable those who seek to defraud federally funded health care programs."

With HHS-OIG's 2 December 2020 release of their Semiannual Report to Congress highlighting an expected recovery in excess of \$4 billion for claims paid during FY2020, the spotlight turns to services that saw the most dramatic regulatory changes.<sup>38</sup>

## 2. How Big Data May Be Used to Support Health Care FCA Cases Based on COVID-19 Changes

HHS-OIG has indicated that it intends to strengthen enforcement efforts by coordinating with other HHS officials and oversight partners to identify vulnerabilities, patterns, and trends of suspicious activity.<sup>39</sup> In addition to widespread coordination, it is clear from recent take-downs and FCA actions that the tools and methodologies used to analyze big data are becoming more sophisticated. Today, data analytics are regularly employed to proactively identify potential instances of fraud.

According to the HHS-OIG Strategic Plan (2020–2025), the OIG will utilize advanced data analytics, artificial intelligence, and machine learning to more effectively perform risk assessments across HHS programs, provider types, and geographic locations to predict vulnerable services that may be susceptible to fraud, waste, and abuse.<sup>40</sup> The DOJ has indicated that the FCA will be among the primary means of combatting fraud relating to the COVID-19 relief package. On 26 June 2020, the DOJ published remarks from the Principal Deputy Assistant Attorney General of the DOJ's Civil Division, Ethan P. Davis, which highlighted the Civil Division's approach to combating fraud related to the various COVID-19 stimulus programs.<sup>41</sup> Davis emphasized that the DOJ's Civil Division will "energetically use every enforcement tool available to prevent wrongdoers from exploiting the COVID-19 crisis," noting that the FCA is one of the "most effective weapons in [the Civil Division's] arsenal."

Utilizing data analytics in 2020 will likely present challenges unique to the context of the public health emergency (PHE). While modern data analytics will continue to support enforcement actions, relying on patterns and trends identified in an ever-changing web of enforcement discretion and regulatory flexibility will not always yield

consistent, reliable results. While the DOJ, HHS-OIG, CMS, and other agencies central to enforcement measures express a strong commitment to identifying and combating fraud related to the COVID-19 stimulus programs, it will be essential to distinguish good-faith actors attempting to comply with regulatory changes from individuals who intend to take advantage of relaxed requirements to commit fraud. Overly aggressive enforcement efforts could stifle expedited production of vital resources that are needed to effectively respond to the PHE.

While there is a general concern that suppliers and providers working to respond to the needs of the pandemic will be overburdened by the daunting task of keeping pace with regulatory flexibilities and policy changes, the DOJ is committed to striking a balance between combatting fraud and enabling and efficient and innovative response to the PHE. In the DOJ's 26 June 2020 remarks, the agency expressed the importance of proceeding carefully, so as "not to discourage businesses, health care providers, and other companies from accessing in good faith the important resources that Congress made available in the CARES Act," providing that the Civil Division "will not pursue companies that made immaterial or inadvertent technical mistakes in processing paperwork, or that simply and honestly misunderstood the rules, terms and conditions, or certification requirements."<sup>42</sup>

## Defense Strategies for Allegations Supported by Extrapolation

Providers that are unfortunately faced with an alleged overpayment supported by sampling and extrapolation have three main avenues for defense:

- (1) disputing the merits of the findings on the sample set,
- (2) examining the sampling and auditing processes, and
- (3) retaining a statistician to challenge the extrapolation process.

### 1. Disputing the Merits of the Sample Set

Whether an extrapolated overpayment by an auditor or an extrapolated damages estimate by the government in FCA litigation, the error rate or falsity rate on the sample set is the key to significantly changing the larger extrapolate findings across the sampling frame (i.e., the full time period of claims under review). The MPIM, Chapter 8, Section 4, provides detailed requirements for CMS contractors in developing an audit plan, a sample frame and set, and a sampling process that is intended to produce a randomly chosen sample set to objectively reflect the findings across the rest of the claims in the sampling frame.<sup>43</sup> The Office of Audit Services for HHS-OIG<sup>44</sup> uses a statistical software called RAT-STATS<sup>45</sup> and is supposed to conduct all auditing and extrapolations in accordance with Government Auditing Standards (GASAS)

developed by Government Accountability Office (GAO).<sup>46</sup> Both the MPIM and GASAS standards are often used and applied by the HHS-OIG and DOJ in establishing a global fraud loss, and these same standards can be used to evaluate weaknesses in the auditing and sampling processes used to determine the findings in the sample set prior to the error rate or falsity rate being extrapolated. Further, as in *Loughren*<sup>47</sup> and *Agape*,<sup>48</sup> every effort should be made in FCA litigation to advocate for a bellwether trial on the sample set before extrapolation, because the government's inability to prove falsity on even a small portion of the sample set can have an impact of reducing the overall damages by millions of dollars. Practically, challenges should be raised to the clinical qualifications of reviewers that made individual claims determinations, to the CMS coverage positions used as the standards for the services or device, and basis for denial is purely a difference of medical opinion.<sup>49</sup>

## 2. Challenging the Sampling and Auditing Process

Providers and counsel also should closely examine the sampling and auditing processes for weaknesses in the government's presumptions from the claims data. Major considerations include conflicting reviews that should be excluded prior to drawing a sample set (i.e., has a portion of the sampling frame been reviewed in a prepayment audit by a MAC or by another CMS contract auditor with contrary findings), was the sample set genuinely random across the spectrum of services/supplies (i.e., were too many sample claims from high value claims selected in comparison to the percentage of high value claims within the sampling frame), or were reviewers provided an improper standard from which to make denials. Any one of these factors that can be shown to not have complied with MPIM and GASAS is grounds for invalidating the sample set.

## 3. Statistical Challenges

The value in retaining an expert witness to challenge the performance of the statistical extrapolation largely depends on the quality of the initial extrapolation process. If the GAO used RAT-STATS, considered the gold standard in statistical sampling and extrapolation, there may be little room to establish error. However, even RAT-STATS extrapolations are only as valid as the original determination on the sample set—establishing that a sample set or error rate is improper invalidates the extrapolation. If an auditor or relator has used statistical extrapolation to support an allegation, challenge the strata selection, confidence interval, and precision interval, as weaknesses in these most easily translate into something an adjudicator will understand—the divisions of review were improperly weighted (strata selection), the findings do not accurately reflect the whole frame (confidence interval), and the findings are not capable of accurate repetition (precision interval). Even HHS-OIG in August 2020 released a report chastising MACs and Qualified Independent Contractors

for not properly evaluating extrapolations based on these primary issues.<sup>50</sup>

## Providers Should Proactively Protect Themselves

Prior to an audit or investigation, providers should arm themselves with their own claims data to reduce risk and in preparation to withstand scrutiny. Providers should take full advantage of CMS programs that provide transparency for claims data analysis of their services in comparison to peers such as Comparative Billing Reports and Program for Evaluating Payment Patterns Electronic Reports.<sup>51</sup> Providers can take a deep dive into Public Use Files to analyze not only their own claims data but claims data of peers across the country.<sup>52</sup> Most importantly, once a provider has an understanding of their data performance according to CMS against peers, an internal analysis of the claims data should be run to determine if CMS reports are accurate or if there are valid explanations for being an outlier compared to peers.

Finally, the basics often prove to be the most useful. Routine review of coverage policies, internal documentation reviews, hiring an external auditor once a year, and documenting corrective action are critical. If an overpayment is discovered, make sure it is repaid timely and documented to stay off the radar.

## Conclusion

In keeping with the anthem of change in 2020, regulators, prosecutors, and providers will be forced to increase their use and competency in data use and analysis as a means to evaluate the dramatic changes to reimbursement regulation. As relators and the government are anticipated to have far greater reliance on the presumptions that data analysis can raise for FCA allegations, providers must equally increase their sophistication and diligence in mining their own data for compliance.

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# Demise of the Treating Physician Rule

By Jacques M. Farhi and Michael Stephen Stretton, III

The most important rule in the adjudication of disability claims before the Social Security Administration—the Treating Physician Rule—does not apply to claims filed after March 27, 2017, as a result of a change in the Regulations: 20 C.F.R. § 404.1520c replacing 404.1527. The Treating Physician Rule was created in New York in the Second Circuit of the United States Court of Appeals (please see the lengthy citation that is presented as part II of this article). The most frequent reason for remands by federal courts is the failure to adequately articulate reasons for rejecting treating source medical opinions and other matters related to treating physicians. This accounts for about 15% to 25% of all remands of Social Security Disability cases by the federal courts in the years 2010 through 2019.

For Social Security Disability applications filed after March 27, 2017, the regulatory Treating Physician Rule ceased to have controlling weight in the adjudication process. This process determines if a disabled person will receive monthly benefits and Medicare; the decision also determines whether the family and even adult disabled children of the wage earner will receive benefits. This decision-making process is overseen by 1,600 Administrative Law Judges and results in hundreds of thousands of administrative hearings annually—which can be appealed to the United States District Courts and results in well over 17,000 cases in those courts annually. This enormous adjudicative process was governed by a simple rule—the opinion of the treating physician should be given controlling weight if it is backed by substantial evidence. In the exact words of the regulation that was in effect until March 27, 2017—“If we find that a treating source’s medical opinion on the issue(s) of the nature and severity of . . . [the claimant’s] impairment(s) is well supported by medically acceptable clinical and laboratory diagnostic techniques and is not inconsistent with the other substantial evidence in . . . [the] case record, we will give it controlling weight.”<sup>1</sup>

This rule was not reached easily—it resulted from much litigation and was adopted by the Social Security Administration in 1991 at the insistence of the federal courts after attempting (and failing) to satisfy federal courts with Social Security Rulings on the matter instead.<sup>2</sup> Rather than fight the matter to the Supreme Court, the Social Security Administration accepted the Rule and made it part of the regulations—thus assuming control over its implementation and ultimately its fate. Whether a person is disabled, that is, whether they are unable to engage in substantial gainful activity (work a 40-hour

workweek) due to a medical condition, is a medical vocational decision—not a legal one. However, two-thirds to three-quarters of the applications are denied at the initial level and then may end up before an Administrative Law Judge after an appeal. The Administrative Law Judge then makes a legal determination if the claimant is disabled or not. From 2008 to 2019, almost 110,000 people died while waiting for the appeal to be heard and decided; another 50,000 filed for bankruptcy between 2014 and 2019 while waiting for a decision.

Those of us who represented claimants in the disability process in the 1990s and 2000s became complacent about the Rule—it seemed like an essential part of what we did, but the reason it was there, and the significance of the proposals to eliminate it, were hardly on the minds of most of us who were busy presenting our cases to the Administrative Law Judges and the federal courts. Some concepts become ingrained in our thinking so that they gain what might be called “authority”—that is the way the legal mind works. As John Chipman Gray explained in his extraordinary treatise on the law, *The Nature and*

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**Jacques M. Farhi is an attorney admitted in New York and Connecticut. He has represented claimants for Social Security Disability and Supplemental Security Income since 1998 and appeared before Administrative Law Judges in 15 states. Farhi studied law at the Touro College, Jacob D. Fuchsberg Law Center; he holds a Master’s degree in Philosophy from the City University of New York, and a Bachelor of Science degree from the Hebrew University in Jerusalem, Israel. He is currently associated with the Law Office of Daniel Berger in the Bronx, New York.**

**Michael Stephen Stretton, III, is an Eligible for Direct Payment Non-Attorney (EDPNA) Social Security disability claimant’s representative who has represented claimants for Social Security Disability and Supplemental Security Income since 2008. He has taught a multitude of courses on Social Security Disability advocacy and on Social Security Administration law and policy. Stretton graduated from the University of California at Riverside where he studied under George Edgar Slusser, Ph.D., in an interdisciplinary baccalaureate program regarding law and speculative fiction. He currently works at Citizens Disability, a national Social Security Disability advocacy company.**



*Sources of the Law* 268 (1909) (revised by Roland Gray in 1921) wherein he quotes Sir G. C. Lewis:

Even when a judge is not following a judicial precedent or the opinion of any jurist, he is constantly acting on authority, on his own authority, so to speak. He remembers having arrived at certain results; he does not recall the reasoning by which he reached them, but nevertheless acts upon them with confidence. “We refer to a foregone process of inquiry, as a ground of present belief, in the faith that it was adequately performed, but without feeling the force of the reasons by which our mind was originally satisfied.”

So it was with the Treating Physician Rule; it pervaded our work for more than 25 years, but we gave little thought to its origin—and then suddenly it was gone. The Rule placed a vital decision in the hands of a claimant’s physician—now that decision is in the hands of an Administrative Law Judge or, at the initial stage, a doctor who never saw the claimant and will spend at most an hour looking at records. In this brief article we will not answer many questions: how did the elimination of the Rule happen and what can be done about it? What we will try to do is to look at the different aspects of this issue in the hope that a conversation will ensue that will lead to action—to consider the restoration of the Treating Physician Rule.

We realize now is not a time for old rules; society is clearly on the dawn of change brought about by the current crisis, the pandemic of 2020. Our legal system is built on constant change—a lawyer presents a case in the afternoon—not knowing what ruling an appellate court made that morning—which could disrupt his argument (this of course was truer a century ago when Gray wrote his book or even a decade ago than it is today with instant computer communication), but the idea is that rules change.

So why argue for this rule? Because it was uniquely developed by the courts to solve a fundamental question and was set aside in a dubious administrative process. The question that the rule addresses was who can possibly decide whether an individual is entitled to benefits that are based on claims containing medical and vocational issues. The Social Security Administration already uses vocational experts in nearly every hearing to help the Administrative Law Judge resolve the vocational issues. Medical experts are not used anywhere near as often as vocational experts in the Social Security Administration’s administrative hearings; when medical experts are used, the medical experts do not even examine the claimant once prior to testifying. Moreover, when a claimant has physical medical conditions that fall under a number of different specialties (from which that claimant receives treatment), a medical expert from a single specialty appears to testify as to that claimant’s physical condition. To give the ultimate decision to a person trained in the law, but not medicine—to a person with no familiarity with the claimant and often without even the benefit of a trained medical professional of a relevant specialty on hand to explain the significance of particular medical findings—reflects a trend in our society to concentrate power in a legalistic bureaucracy that is increasingly remote from the people it is meant to serve. It also degrades the appearance of awarding benefits based upon objective medical facts and reasonable medical inferences.

The basic argument for changing the Treating Physician Rule according to HALLEX I-5-3-30, Revisions to Rules Regarding the Evaluation of Medical Evidence, after 25 years, is that:

Healthcare delivery has changed dramatically since the 1991 rules were implemented. Many people now receive healthcare from coordinated and managed care organizations instead of a single

treating physician. People typically visit multiple medical professionals, including primary physicians, specialists, and nurse practitioners, and they do so in a variety of medical settings, such as managed care and specialty clinics, hospitals, ambulatory care centers and public healthcare centers. As a result, people are less likely to develop a sustained relationship with a single treating physician.

Yet it is the experience of the authors, one of whom practices in the Bronx, N.Y. (one of the poorest counties in the country, with the most patients receiving medical care through large hospitals and organizations)—that people with longstanding disabilities receive care from “single treating physicians.” People with multiple sclerosis, heart conditions, orthopedic problems, severe psychiatric ailments—have the same doctors in these large institutions treating and following them for years. Sometimes these doctors become so frustrated with the repeated denial of their patients that they volunteer to come to the hearings and testify with no compensation. When we see these doctors’ reports over time describe a progressively worsening condition, we know that true physicians are not deterred by large organizations from treating individuals and forming an understanding of their condition—in fact, the last 25 years has resulted in an increase in the practice of specialists following cases, not the reverse.

The other argument for changing the Treating Physician Rule according to HALLEX I-5-3-30, Revisions to Rules Regarding the Evaluation of Medical Evidence, is that:

SSA’s remand data from both the Appeals Council . . . and Federal courts revealed that consideration and evaluation of opinion evidence has consistently remained one of the highest reasons for remand at both levels. The Federal courts differed in how strictly they have interpreted the articulation requirements for evaluating opinion evidence and developed varying standards for determining what constitutes a treating physician relationship and how SSA must address multiple opinions from multiple treating sources. The various approaches moved SSA’s adjudication away from the content of medical opinions and towards weighing treatment relationships against each other. Consequently, the reviewing courts have focused more on whether SSA sufficiently articulated the weight . . . [given] treating source opinions rather than on whether substantial evidence supported a final decision.

What does this mean? That federal court judges and the Appeals Council cannot analyze treating physicians’

opinions and decide if the criteria to give these opinions controlling weight are met; that the Administrative Law Judge’s have difficulty articulating their reasoning—and thus there are a lot of remands. The complexity of the legal issues in a Social Security Disability case are not overwhelming—1,600 Administrative Law Judges are highly paid to adjudicate these cases; it is not unreasonable to expect that these judges can be trained to handle the key issue in these cases. As a practical matter deciding if an opinion is consistent with the medical evidence and if the treating relationship meets the required criteria is certainly easier than reaching a medical/vocational assessment based on thousands of pages of evidence, but with no medical training and no direct knowledge of the claimant.

The basis for the change of the Rule is a report by a small government agency that exists to create research for the federal bureaucracy—the Administrative Conference of the United States. This agency issued two reports on April 3, 2013: “Achieving Greater Consistency in Social Security Disability Adjudication: An Empirical Study and Suggested Reforms” and a report specifically about the Treating Physician Rule—“SSA Disability Benefits Programs: Assessing the Efficacy of the Treating Physician Rule.” Both reports were authored by Harold J. Krent, a law school dean, and Scott Morris, an associate dean and professor of psychology—no medical doctor was involved in authoring these reports. The first report is 86 pages with 14 recommendations on how to improve the adjudication process; the second report is more than 60 pages with lengthy footnotes and many appendices. This second report calls for revision or elimination of the Treating Physician Rule, especially the decisive “controlling weight” aspect. A subsequent report issued on July 18, 2016 by the Administrative Conference of the United States—“A Study of Social Security Litigation in the Federal Courts”—which, we believe, inadvertently reveals the reason for the Administrative Law Judges difficulty with the articulation of the Treating Physician Rule. This report shows that the Administrative Law Judges use a “just in time approach” to preparing their cases. The Administrative Law Judges look over six to eight cases, a day to a week before the hearing. The Administrative Law Judges are expected to do 10–20 hearings a week. “A union contract does not permit Administrative Law Judges to work overtime, so this schedule has implications for the amount of time Administrative Law Judges have for each case,” the report notes. Many Administrative Law Judges do not look at every page of the file before (or after) they conduct a hearing, the hearings typically lasts 15 minutes to an hour. Some of these hearings are done by video teleconference (of course, since the March 2020 closure of all the Social Security Administration offices, the hearings have been done by telephone).

The Administrative Conference of the United States report states that the Administrative Law Judge does not write the actual decision—this is done by a staff decision

writer, usually an attorney. Once the decision is written, the Administrative Law Judge reviews it for about 30 minutes. Thus, the 2016 report reveals the Administrative Law Judge spends about one to two hours studying a case, 15 minutes to an hour hearing the case, and then makes a decision. The decision is written by a staff person and then reviewed and signed by the Administrative Law Judge. *Could this process be the reason that Administrative Law Judges have problems articulating the Treating Physician Rule and the reason federal court judges are so confused by the Administrative Law Judge decisions? Was throwing out the Rule (rather than looking at the implementation) the correct solution?*

Judges in the federal courts adjudicate on countless issues; the issues in a Social Security Disability case are very limited. The different Circuit courts may resolve issues in different ways. We have a legal system designed to resolve differences between the Circuits—and the Social Security Administration was urged to use that system to get to a single national, acceptable standard by having the Supreme Court resolve the differences between the Circuit Courts. The Social Security Administration declined and instead accepted the Treating Physician Rule and promulgated a version acceptable to the Social Security Administration in the regulations. In 2017—25 years after the Social Security Administration resolved the issue—the Rule is gone; leaving the Courts now the task of deciding how to resolve precedents that were made in a different era, or make a series of new decisions that will take years to percolate upward through the District and Circuit Courts. If the Rule is the valid way to adjudicate disability cases, then this litigation process will be a most painful delay to hundreds of thousands of applicants and will stretch over many years the just resolution of their cases.

We believe that no ruling of the Second Circuit has impacted more people directly than the Court's requirement that the Social Security Administration create a federal Treating Physician Rule. This was accomplished in a series of class action cases (*i.e.*, *Schisler I*,<sup>3</sup> *Schisler II*,<sup>4</sup> and *Schisler III*<sup>5</sup>) that began in 1980 and culminated in 1991 with the adoption of a regulation. The Second Circuit caselaw at the time of *Schisler I* gave substantial weight to the opinions of treating physicians in Social Security disability benefit cases as a rule.<sup>6</sup> The Social Security Administration had not at that time promulgated any comprehensive regulation concerning the weighing of medical opinions and the Department of Health and Human Services chose not to acquiesce to the Second Circuit's Treating Physician Rule and failed to ever seek Supreme Court review of the Second Circuit's Treating Physician Rule. The result was that the United States Court of Appeals for Second Circuit and district courts within the Second Circuit were faced with a large volume of appeals asserting the Treating Physician Rule as a ground for overturning denials of benefits by Department of Health and Human Services.<sup>7</sup> Congress got frustrated with the Department of Health and Human Services' failure to either acquiesce or seek Supreme Court review.<sup>8</sup>

One district court ordered the Secretary of the Department of Health and Human Services to apply the Treating Physician Rule of the Second Circuit in all cases, which was an unprecedented intrusion into a federal agency's right to non-acquiescence.<sup>9</sup> As Circuit Judge put it

[i]t thus appeared that HHS was non-acquiescing in the treating physician rule not as a matter of principle—which could have been resolved by seeking review in the Supreme Court—but as a means of discouraging claimants who relied upon the rule. This creation of unnecessary legal hurdles was understandably perceived as an abuse of process.<sup>10</sup>

So at the time when *Schisler I* was argued, the counsel for the Secretary of the Department of Health and Human Services represented to the United States Court of Appeals for Second Circuit that the Second Circuit's version of the Treating Physician Rule was being followed by the Social Security Administration.<sup>11</sup> As a result of that representation, the United States Court of Appeals for Second Circuit directed the Secretary of the Department of Health and Human Services to inform its adjudicators in the Social Security Administration by appropriate publication of that policy.<sup>12</sup> This rather unusual form of relief was ordered because the Department of Health and Human Services' adoption of the rule had been expressed by counsel for the Secretary of the Department of Health and Human Services to the United States Court of Appeals for Second Circuit, but it was hardly evident to the Social Security Administration's adjudicators. The United States Court of Appeals for Second Circuit left "to the district court the task of fashioning the precise order to accompany the remand."<sup>13</sup>

The Secretary of the Department of Health and Human Services then proposed a Social Security Ruling that was modified by the district court to bring it into conformity with our instructions requiring a verbatim restatement of the Treating Physician Rule.<sup>14</sup> The Secretary of the Department of Health and Human Services appealed, claiming that the ordered revisions exceeded the district court's authority. In upholding the district court's authority to order the revisions in *Schisler II*, to the United States Court of Appeals for Second Circuit further articulated the Treating Physician Rule. In particular, we held that the nature of the relationship between the physician and the claimant, rather than the relationship's duration, was "determinative" of whether the physician was a "treating source" under the Treating Physician Rule and that "[t]he opinions of non-examining medical personnel cannot, in themselves and in most situations, constitute substantial evidence to override" a treating physician's opinion.<sup>15</sup> In *Schisler II*, the United States Court of Appeals for Second Circuit upheld the district court's version of the Secretary's draft to the extent that it agreed with the Second Circuit's Treating Physician Rule.

The Secretary of the Department of Health and Human Services then issued the regulations entitled “Standards for Consultative Examinations and Existing Medical Evidence”<sup>16</sup> after notice and comment periods. These regulations set forth criteria for evaluating the medical opinions of treating physicians in disability benefit claims proceedings that differed from the Second Circuit’s Treating Physician Rule. These new regulations were promptly challenged by both the third *Schisler* class action lawsuit and the *Aldrich* class action lawsuit, but both district courts held that the new regulations were binding in administrative proceedings though stated that the Second Circuit’s caselaw-based Treating Physician Rule continued to hold an overriding and paramount status and effect in disability proceedings on appeal in federal courts and, indeed, the Second Circuit also did so declare:

Indeed, we expressly noted that if the Secretary wanted to “elaborate on [that] rule in ways not expressly authorized by our caselaw ...[,] he should resort to the customary administrative processes.” *Schisler II*, 851 F.2d at 45. In the instant matter, the Secretary has resorted to “the customary administrative processes” and has issued valid regulations. Because the Secretary has complied with the applicable rule-making procedures, we must give the new regulations “the deference traditionally shown” to the Secretary’s regulations.<sup>17</sup>

And now, 28 years later—for Social Security Disability applications filed after March 27, 2017—the Treating Physician Rule ceased to have controlling weight in the adjudication of disability cases. The Social Security Administration accomplished this by the same “customary administrative processes” that were used to circumvent obtaining a clear ruling by the Supreme Court on this matter in 1991. The question now is whether this generation of disability advocates will have the skill and determination to bring the rule back—it is sorely needed.

## Endnotes

1. 20 C.F.R. § 404.1527(c)(2).
2. See *Schisler v. Bowen*, 851 F.2d 43 (1988); *Schisler v. Sullivan*, 3 F.3d 563 (1993).
3. *Schisler v. Heckler*, 787 F.2d 76 (2d Cir.1986) (“*Schisler I*”).
4. *Schisler v. Bowen*, 851 F.2d 43 (2d Cir.1988) (“*Schisler II*”).
5. *Schisler v. Sullivan*, 3 F. 3d 563 (2d Cir. 1993)(“*Schisler III*”).
6. See, e.g., *Bluvband v. Heckler*, 730 F.2d 886, 892-93 (2d Cir. 1984); *Gold v. Secretary of Health, Educ. and Welfare*, 463 F.2d 38, 42 (2d Cir. 1972).
7. *Schisler I*, 787 F.2d at 82.
8. *Schisler I*, 787 F.2d at 82–83.
9. *Stieberger v. Heckler*, 615 F. Supp. 1315 (S.D.N.Y. 1985), *vacated sub nom. Stieberger v. Bowen*, 801 F.2d 29 (2d Cir. 1986).
10. *Schisler III*, 3 F.3d at 565.
11. *Schisler I*, 787 F.2d at 83.
12. *Schisler I*, 787 F.2d at 84.
13. *Schisler I*, 787 F.2d at 85.
14. See *Schisler II*, 851 F.2d at 44–45 (quoting the district court).
15. *Schisler II*, 851 F.2d at 45–47.
16. 56 Fed.Reg. 36,932 (1991).
17. *Schisler III*, 3 F.3d at 569.

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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.

## Diversity

Lillian P. Mosley  
Community Service Society of New York  
633 3rd Ave Fl 10  
New York, NY 10017-6701  
lillianmosleyesq@gmail.com

## E-Health and Information Systems

Daniel Meier  
Benesch Friedlander Coplan & Aronoff  
Continental Plaza II  
411 Hackensack Ave Fl 3  
Hackensack, NJ 07601-6323  
dmeier@beneschlaw.com

Nathan G. Prystowsky  
Axiom  
16 N Broadway Apt 2N  
White Plains, NY 10601-2223  
nprystowsky@icloud.com

## Ethical Issues in the Provision of Health Care

Lawrence R. Faulkner  
The ARC Westchester  
265 Saw Mill River Rd Fl 3  
Hawthorne, NY 10532-1509  
faulknerlawrence@gmail.com

Brendan S. Parent  
NYU School of Medicine  
227 E 30th St Ste 721  
New York, NY 10016  
brendan.parent@nyu.edu

## Health Care Litigation

Linda J. Clark  
Barclay Damon LLP  
80 State St  
Albany, NY 12207-2541  
lclark@barclaydamon.com

Jeffrey J. Sherrin  
O'Connell & Aronowitz PC  
54 State St Fl 9  
Albany, NY 12207-2527  
jsherrin@oalaw.com

## Health Care Providers and In House Counsel

Margaret J. Davino  
Fox Rothschild LLP  
101 Park Ave Fl 17  
New York, NY 10178-1700  
mdavino@foxrothschild.com

## Health Law Legislative Issues

Mark R. Ustin  
Farrell Fritz, P.C.  
Albany, NY  
mustin@farrellfritz.com

## Long-Term Care

Jane B. Burke  
Hodgson Russ LLP  
677 Broadway, Ste 301  
Albany, NY 12207-2986  
jbburke@hodgsonruss.com

## Medical Research and Biotechnology

Alex C. Brownstein  
BioScience Communications  
250 Hudson St, Fl 9  
New York, NY 10013-7634  
alex.brownstein@biosic.com.net

Samuel J. Servello  
New York, NY 10003  
samservello.barmail@gmail.com

## Membership

Salvatore Russo  
Fox Rothschild LLP  
101 Park Ave Ste 1771  
New York, NY 10178  
sjrusso@foxrothschild.com

Jorge Luis Rivera  
Northwell Health  
27005 76th Ave Ste B305  
New Hyde Park, NY 11040-1402  
jlr2245@columbia.edu

## Payment, Enforcement & Compliance

William P. Keefer  
Phillips Lytle LLP  
Buffalo, NY  
wkeefe@phillipslytle.com

Sandra C. Maliszewski  
Maimonides Medical Center  
Brooklyn, NY  
smaliszewski@maimonidesmed.org

## Professional Discipline

Douglas M. Nadjari  
Ruskin Moscou Faltischek, PC  
1425 Rxr Plz  
Uniondale, NY 11556-1425  
dnadjari@rmfpc.com

John. J. Barbera  
Martin Clearwater & Bell LLP  
245 Main St  
White Plains, NY 10601-2411  
barbej@mcblaw.com

## Public Health

Thomas Merrill  
New York, NY  
tgmerrillnyc@gmail.com

Dr. Mary Beth Quaranta Morrissey  
Fordham University GHIMC  
400 Westchester Ave  
West Harrison, NY 10604-2908  
mamorrissey@fordham.edu

## Young Lawyers

Brenda Baddam  
Barclay Damon  
80 State St  
Albany, NY 12207-2541  
brendabaddam@gmail.com

Cassandra Rivais DiNova  
Rivkin Radler LLP  
66 S Pearl St Fl 11  
Albany, NY 12207-1533  
cjrivais@buffalo.edu

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