From Emergency Orders to Regulatory Reform in Post-Emergency New York

By Robert N. Swidler

"Everyone has to think outside the box. Because there is no box."
NY Governor Andrew Cuomo, April 26, 2020

Starting in March 2020, New York State began waiving or otherwise relaxing numerous health care laws and regulations[1] in order to help fight the COVID-19 pandemic. The state accomplished this largely through executive orders and agency directives. By April, the Governor and agencies also started to impose new obligations on health care providers by issuing enforceable directives and emergency regulations.

These opposite regulatory levers—the waiver and the directive, the brake and the pedal—were and are being used to meet the new and shifting exigencies of COVID-19. But together they have changed the regulatory landscape rather dramatically. As the COVID-19 emergency recedes, policymakers will need to consider: Which waivers and directives should be allowed to expire, which should endure? Or, in the case of waivers, the issue is really: which suspended regulations should be allowed to spring back to life, and which should be retired?

Background

Governor Cuomo issued his first COVID-19-related executive order, EO 202, on March 7, 2020. He declared a "State disaster emergency" for the entire State of New York and provided that it would be in effect until September 7, 2020.[2] The executive order (EO) then suspended or modified provisions of the Education Law, Executive Law, General City Law, Highway Law, Public Authorities Law, Public Health Law, State Finance Law, Transportation Law, Vehicle and Traffic Law and Village Law, as well as DOH and SED regulations and the NYC Code.

Clearly, on that date we entered a new era.

The EO was issued pursuant to NY Executive Law § 28, which had been amended just a few days previously to give the Governor rather stunning emergency authority.[3] Previously the Governor had the authority only to "temporarily suspend specific provisions" of laws or regulations that hindered responding to the disaster. The amendment expanded his authority to include the power "to issue any directive necessary to cope with the disaster" and to provide procedures to enforce the directive. Certain limits, including time limits, continued to apply.

From that day until this writing (June 5, 2020) the Governor has issued 36 COVID-19-related executive orders. Those orders included *roughly 375 separately bulleted emergency waiver provisions and/or directives.* That is an average of four waivers/directives per day for over three months. That remarkable trend will likely continue for at least a while longer. And this is an undercount since many of the bulleted provisions waive multiple regulations.

The largest number of emergency waivers/directives—about 150 and counting—are health care-related regulations.

Health Care-Related Regulatory Waivers

So far, the major categories of health care-related EO waivers and suspensions relate to:

- Professional licensure / scope of practice requirements;[4]
- Collecting and testing samples;[5]
- Expedited discharge requirements;[6]
- Documentation requirements;[7]
- Virtual meetings rather than in-person meetings;[8]
- Certificate of Need (CON) requirements;[9]
- Promoting telemedicine;[10] and
- Liability protections.[11]

In addition, health-related agencies acted separately to suspend or relax previous requirements.[12]

Health Care-Related Directives

While removing regulatory requirements from providers with one hand, state government has been adding them with the other. Major new directives have related to:

- Mandating increases in bed and ICU capacity;[13]
- Visitation and notification restrictions and requirements;[14]
- Commandeering medical equipment and supplies;[15]
- Testing health care staff;[16] and
- Constraints on discharges.[17]

The Opportunity

This awful pandemic appears to be slowly receding in New York State. Waivers and other time-limited measures

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will expire. Without further steps, the full pre-COVID-19 panoply of regulations will spring back into place. That would be beyond unfortunate. Policymakers now have an unprecedented opportunity to review the list of waived regulations and our experience under the waiver, think anew about each regulation's benefits and burdens, and consider whether it should be restored, changed or repealed.

To be sure, every one of the waived health regulations had an important purpose. Each was intended to promote quality of care and access, protect patient safety and privacy, control costs or achieve some other public policy aim. Yet the Governor and/or the responsible agency concluded that the regulation in question detracted from the battle against COVID-19. It may have impeded the ability to deploy staff and resources to where they were needed. In other cases, compliance was impossible or impractical under the circumstances.

Whatever the reason it was waived, it would be a mistake and a lost opportunity to simply allow waived rules to return without scrutiny. A government that issues regulations has the responsibility to periodically review their value and effectiveness. New York, to its credit, recently undertook a partial exercise in that regard by convening a Medicaid Reform Team (MRT), which was charged to cut costs of the Medicaid program.

The pandemic has generated an even greater need for a broad and rigorous regulatory review:

- *Financial pressure on providers.* Hospitals and other health care facilities and providers have been financially stricken by the emergency. They are being forced to cut costs in ways that were unthinkable before COVID-19. Many find themselves having to terminate, furlough or reduce the hours of both clinical and administrative colleagues. They are no longer staffed or able to comply with every regulatory requirement that existed before the emergency.
- *Financial pressure on government.* State government has been similarly injured by COVID-19. For the foreseeable future it too will be less able to perform all the administrative and enforcement functions that regulations require of it. More regulations require more regulators.

  As an aside, state agencies seem to be increasingly resorting to a problematic technique to make up for their reduced oversight capacity: They are compelling facility officials to attest or certify their compliance with regulations. By this technique, it can bootstrap the modest penalty for a regulatory violation into far more intimidating criminal or civil penalties for perjury or falsely certifying. A government with regulatory resources that match its regulatory responsibilities would not need to resort to that kind of tactic.
- *The need for additional regulations.* As noted above, emergency orders have not simply waived regulations, they have imposed new directives. The pandemic is far from over, and it will reveal the need for further directives or regulations. For instance, the pandemic is likely to prompt further requirements relating to pandemic and other emergency preparedness and stronger infection control practices. These requirements will increase the compliance responsibilities of providers, and the oversight responsibilities of the state.

The final point demonstrates that this is not your typical polemic against overregulation; it is rather a plea to use the moment to eliminate a regulation when its cost or burden outweighs its benefit, while supporting new regulations that are more urgently needed to address current circumstances. It is a plea to use both of the levers mentioned at the outset of this article, and not just to grandfather in old regulations while adding new ones.

Turning then to the categories of waivers mentioned previously, consideration should be given to the following:

- *Professional licensure / scope of practice requirements.* To be sure, every one of the waived regulations had a valid quality purpose—and a constituency that will guard it. And some of these waivers seem more drastic than others. But at the very least, the rationale for each of these requirements needs to be re-examined before it is reinstated in its prior form—especially now that we know these requirements can serve as a barrier to access in an emergency. For instance, there should be expanded ability to rely upon out-of-state clinicians, particularly for telemedicine, in a safe and accountable manner. Moreover, emergency rules should be preserved, or new rules implemented, to allow clinicians to practice at the top of their licensure, and that allow trained non-clinicians to perform tasks that should not require licensure (e.g., the introduction by cardiovascular technicians of contrast material into a pre-inserted line.).
- *Collecting and testing samples.* The pandemic will not go away soon. Here again, policymakers need to consider whether a broader group of health care colleagues should be enlisted in the ordering, collection and testing of samples than was allowed previously. For example there should be a permanent change in the Education Law and regulations to allow RNs to administer COVID-related testing for both virus and antibodies upon a non-patient specific order of a physician or NP along with all of the requirements that exists today for a protocol (similar to HIV testing and Hepatitis C testing).
- *Expedited discharge requirements.* Regulatory barriers to discharge drive up costs and do a disservice

to patients. There is a need to see how well discharges were accomplished during the COVID-19 emergency and whether there is a strong enough reason to reinstate old rules.

- *Documentation requirements.* This is an area where agencies can make some long overdue reforms. There needs to be tough scrutiny of documentation requirements including a reduction in the number of required reports; a reduction in the number of fields or queries in each report; the elimination of all or nearly all requirements to submit documents on paper the elimination of all or nearly all requirements to submit original signatures; the elimination of all or nearly all notarization requirements.
- *Virtual meetings rather than in-person meetings.* Virtual meetings are more convenient, eliminate travel expenses, and reduce infection risk. Improvements in meeting technology makes these feasible and close in feel to in-person meetings. Policymakers should continue to expand the option for companies to hold required meetings and perform other functions through virtual meetings.
- *CON requirements.* New York State could use this occasion to reconsider the list of actions that require a CON, and look for ways to simplify and expedite the process. The emergency offers an example—when the state is urgently trying to increase capacity of a service—or for that matter urgently trying to reduce capacity of a service—it could create a short-form application and fast-track administrative process to promote that goal.
- *Promoting telemedicine.* Recent events are showing that patients accept and, in many instances, prefer telemedicine visits. They are convenient, they reduce infection risk; they are cost-effective; and they can offer treatment by specialists and expertise that the patient would not otherwise be able to see. Policymakers need to foster the growth of this approach to the delivery of care through regulatory relief as well as adequate reimbursement. Telemedicine needs to be promoted not only for primary and acute medical services, but for behavioral health; social work; home health; and care coordination.
- *Liability protection.* Certain liability protection principles should be extended beyond the COVID-19 emergency. In particular, there is a strong case to be made to allowing a physician to enter a DNR order without patient or surrogate based on futility or no medical benefit even in ordinary circumstances—physicians should not have to offer a nonbeneficial treatment. But that argument becomes compelling when the futile resuscitation would expose the responding staff to a highly contagious disease. There is no reason to await an emergency order to implement this principle—it should be built into the law. Similarly, immunity should be afforded to health care facilities and staff who need to carry out ethically accepted triage principles in an emergency. That immunity should be established in advance of a crisis and activated when specific emergency criteria are met. It should not depend on an executive order.

As Governor Andrew Cuomo has stated: "It is time to think out of the box. There is no box." This is the time to critically review health care regulations, preserve or even enhance rules that offer cost-effective protection for patients and the public, and identify those that should be changed or dropped. The review should not be limited to those regulations that were waived during the emergency. Nor should it be limited to state regulations (COVID-19 is revealing changes that are urgently needed to EMTALA, HIPAA, Stark, Medicare conditions of participation and more). But a review of New York's emergency waivers is a convenient and logical place to start.

Endnotes

1. For simplicity, this article will use the "regulation" to refer generically to statutes, regulations, ordinances and other enforceable governmental directives).
2. *See* https://www.governor.ny.gov/executiveorders.
3. 2020 N.Y. Laws ch.
4. EOs 202, 202.1, 202.10, 202.13, 202.14, 202.15.
5. EOs 202.1, 202.24, 202.32, 202.36.
6. EOs 202, 202.1, 202.5.
7. EOs 202, 202.5, 202.10, 202.14.
8. EOs 202, 202.5.
9. EOs 202, 202.1, 202.5, 202.10.
10. EOs 202, 202.2, 202.5.
11. EO 202.10 bullet 9; NYP EO 202.10 bullet 9 waived/retrofitted New York's good Samaritan laws to protect certain health care professionals from civil liability for certain acts and omissions during the emergency. The Emergency or Disaster Treatment Protection Act, Public Health Law 30-D, enacted as part of the FY 2021 budget, protects certain health care facilities and health care professionals from civil and criminal liability for certain acts and omissions during the emergency.
12. For example, the Department of Financial Services relieved providers of certain health plan prior approval requirements. See Supplement No. 1 to Insurance Circular Letter No. 8 (2020). April 22, 2020.
13. EO 202.10.
14. EOs 202.11, 202.13, 202.18.
15. EOs 202, 202.1, 202.5.
16. EO 202.30.
17. EO 202.30.