

Still **TANGLED UP IN RULES**

UNTYING THE KNOT OF REGULATIONS
THAT HINDER HEALTH CARE
INNOVATION AND CHANGE

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Healthcare Association
of New York State

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Health care reform at the state and federal level, including new reimbursement methods that incentivize novel models of care delivery and link payment with quality performance, is helping to transform the health care system. However, as providers work to extend the focus of care to include wellness and prevention of illness, they face significant reimbursement reductions and regulatory roadblocks that hinder reform.

The current regulatory structure is often a barrier to progress because it has not kept pace with the changes occurring within the health care system, and remains rigid where it should allow flexibility and innovation. To successfully achieve efficient, patient-centered, coordinated care, health care providers need flexibility to design health care delivery models that will work in their communities.

It is time to modernize a cumbersome Certificate of Need (CON) program, eliminate duplicative inspections, and update workforce and scope of practice regulations to reflect the reality of health care today.

Rather than rely on national standards designed to ensure the provision of quality health care services, New York State has long chosen to add its own standards. This New York State approach has proven costly to providers and has not shown improvement in the quality of care compared to the rest of the nation. Many of the rules were crafted in the late 1980s and have not been updated since then, though the health care industry has evolved dramatically during that period. New York State rules have simply not kept up with the times.

This paper summarizes some of the barrier-creating rules that are hindering health care reform and diverting limited resources away from patient care.

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Certificate of Need (CON)

Foremost on the list of barriers is the state's CON program. While originally designed to control and slow growth of the regulated sector of the health care delivery system, CON now impedes the progress of needed reconfiguration.

HANYS has embarked on a multi-year effort to improve the CON process and has achieved notable success: legislation passed in 2011 and enacted by Governor Cuomo designed to reduce the volume of required CON applications is now being implemented. This must be done in the broadest manner to provide as much relief as possible, and more needs to be done to further streamline the cumbersome CON process.

CON processing delays result in increased construction costs and delayed patient access to modern treatment modalities and facilities. The CON process needs to incentivize rather than block reconfiguration and should be designed to improve timely access to the most current and effective treatments.

All providers, including those not licensed by the Department of Health (DOH), must come under the same set of rules. The Planning Committee of the Public Health and Health Planning Council has been charged with developing a streamlined and re-purposed CON process. HANYS is an active participant in that effort. However, any meaningful change that might result from this process is months, possibly years, away.

HANYS' RECOMMENDATIONS

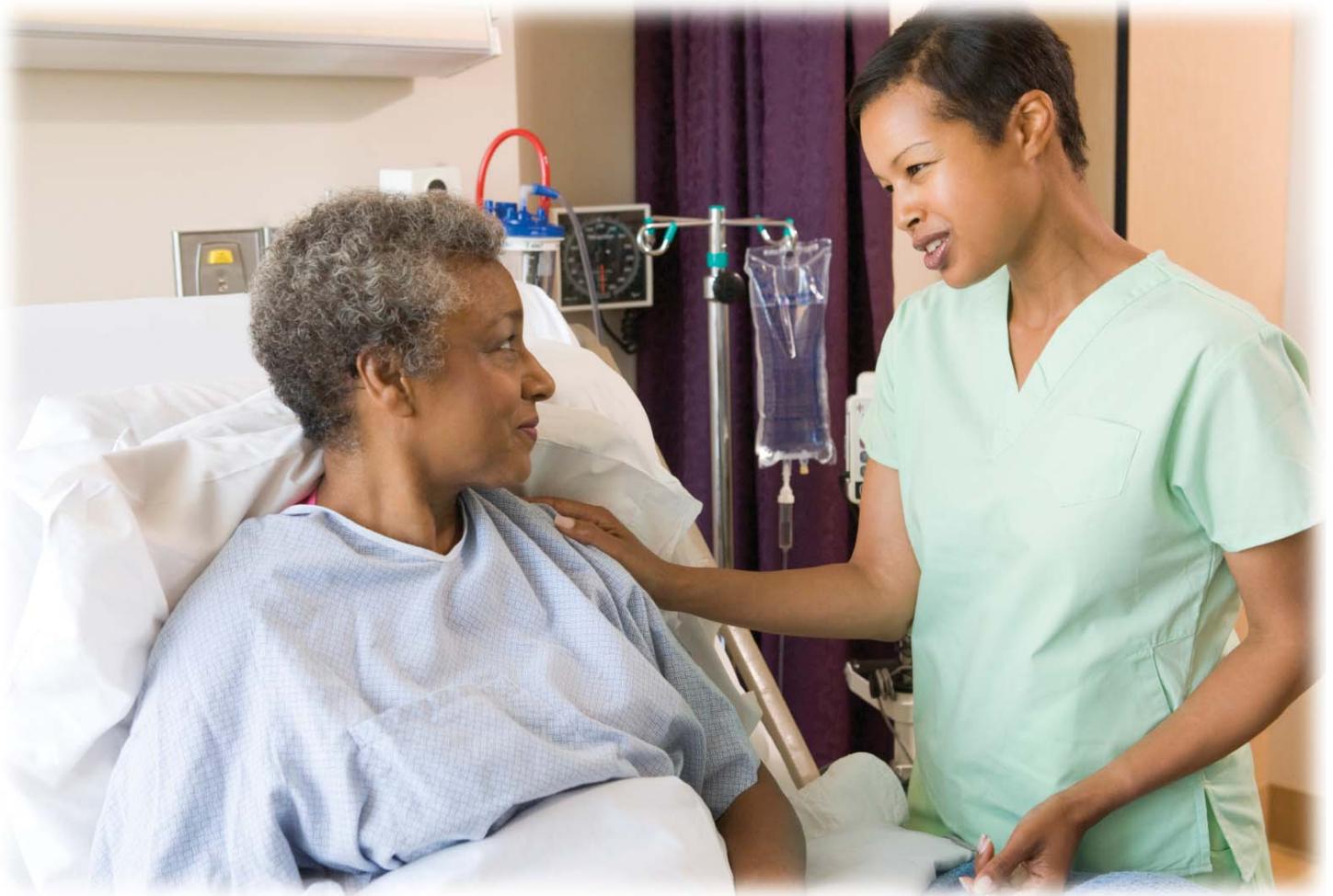
- Eliminate the CON requirement for any service that can be provided by a non Article 28-licensed provider. For example, private physicians seeking to partner with their local hospitals should not face onerous structural requirements imposed on the hospital sector, which can inflate costs for developing new primary care capacity several-fold.
 - There should be a 60-day DOH response requirement for any CON that proposes facility reconfiguration or outpatient service expansion or creation. If DOH does not respond within 60 calendar days, the proposal should automatically be deemed approved.
 - DOH should accept independent expert certification if a pre-opening survey cannot be completed within two weeks.
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Improve Observation Services

Even as the state is seeking a reconfiguration of institutional health care delivery, it continues to impose inflexible rules on inpatient providers of care. A recent example is the rules covering observation services linked to Medicaid payment. These rules are different from other government and private insurer rules for observation. The new rules require a designated observation area, which would require costly construction for many hospitals, together with other staffing and operational restrictions—or Medicaid will not reimburse the hospital for observation services. Other payers focus on the care provided to the patient, not the location where the patient is housed, to reimburse for services.

HANYS' RECOMMENDATION

- Modify the state observation services requirements for Medicaid to be the same as federal Medicare observation requirements.
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Workforce Flexibility/Scope of Practice

At a time when reconfiguring the health care delivery system is being mandated, the available clinical workforce must be used flexibly and practitioners need to be utilized to the fullest extent possible. Outdated hospital code requirements and scope of practice limitations restrict flexibility at a time when flexibility should be increased.

REGISTERED NURSE “ONE-YEAR” RULE

For example, Part 405 of Title 10 New York Codes, Rules, and Regulations (NYCRR) requires that a registered nurse must have one year of clinical experience outside the emergency department (ED) before he or she can work in an ED. This rule was created in the late 1980s as a proxy for ensuring qualified nursing staff in EDs. Today, the recognized standard, nationally, is one that involves a mentoring program for new nurses in the ED to provide training and experience needed to ensure good nursing care. Current New York State regulations prohibit this proven approach.

HANYS’ RECOMMENDATION

- Eliminate the one-year clinical experience requirement for nurses to work in an ED.
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PHYSICIAN HEALTH ASSESSMENTS

Currently, Part 405 of Title 10 NYCRR requires the performance of a health assessment for physicians to practice in hospitals. Physicians who provide consultations from a remote location via telemedicine never come in contact with patients seen through that modality. Although the New York State hospital code was changed for physicians who provide telemedicine consultations from areas beyond New York’s borders, physicians who provide the same consultations from within the state are still required to have the patient’s health assessed by the hospital where the patient is located.

HANYS’ RECOMMENDATION

- Eliminate the requirement that physicians in New York State who provide telemedicine consultations complete a health assessment at the remote site.
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ALLOW HOUSE CALLS

To retain and recruit physicians in rural and under-served communities, hospitals need to employ them. However, once employed by a hospital, physicians are no longer allowed to treat patients in the patients' homes or in nursing homes. This means that elderly, infirmed, and disabled patients must be transported, many by ambulance, to hospital clinics or EDs to receive routine care. Freestanding clinics licensed by the state and certified by the federal government as Federally Qualified Health Centers can, by federal rules, offer practitioner "house calls." Other freestanding clinics and hospitals licensed by the state should be afforded the same authority. That would better serve the patients they see and would reduce costs. Authorizing practitioner house calls is a state policy determination.

HANYS' RECOMMENDATION

- Authorize physicians employed in all Article 28 licensed hospitals and clinics to provide and be paid for making house calls.
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UNIVERSAL HEALTH CARE WORKER

In New York, home care and personal care aides are state-defined roles with separate educational requirements. A "universal worker" curriculum would provide all the education, skills, competency testing, and verifications to prepare/allow a caregiver to be hired as a paraprofessional in any setting. The only additional preparation or content necessary would be an organizational-specific "orientation" to policies and procedures. This would require state and federal reform, as the certification of nurse assistants in nursing homes is defined at the federal level.

HANYS' RECOMMENDATION

- DOH should work with the federal government, health care employers, employees, and their advocacy organizations to develop policies that create, implement, and promote a universal health care worker education curriculum. One such project is currently being demonstrated in Rochester by the Visiting Nurse Service and collaborative partners.
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LICENSING REQUIREMENTS FOR CERTAIN HEALTH CARE PROFESSIONALS

Several professions licensed through the State Education Department (SED), including pharmacists, must be United States citizens to practice in New York. This limits providers' ability to recruit qualified individuals coming into the country with H1-B visas.

HANYS' RECOMMENDATION

- Licensure requirements must be modified to permit employment of qualified professionals with H1-B visas or other legal credentials to create the largest pool of qualified professionals possible.
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Outdated Requirements

Rural hospital emergency departments experiencing fewer than 15,000 patient visits per year can be staffed by nurse practitioners and physician assistants as long as a physician can be available on-site within 30 minutes. Meeting the 30-minute timeframe is not always possible in some rural areas of the state. The state should accept a physician consultation via telemedicine as fulfilling this requirement.

HANYS' RECOMMENDATION

- Allow the physician on-site response requirement for hospitals that staff their emergency departments with physician assistants and nurse practitioners to be met through telemedicine.
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Specialty consultations provided via telemedicine can help provide access to needed services in areas of the state where specialists do not practice. However, the hospital where the patient needs a specialist's consultation is statutorily obligated to perform a peer review of that specialist's work. That becomes very challenging because the reason the specialist consultation is needed via telemedicine is because there are no peers at the receiving hospital. The mandated peer review at the hospital where the specialist resides should be able to be accepted at the hospital receiving the consultation as fulfillment of the statutory requirement. The peer review requirement is in Public Health Law Section 2805.

HANYS' RECOMMENDATION

- Allow the peer review obligation placed on hospitals that receive physician consultations by telemedicine to be fulfilled through peer review activities conducted at the hospital that provides the consultation.
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IMPROVE DOCTORS ACROSS NEW YORK

Retention and recruitment of physicians to practice in New York State, especially in rural and under-served communities, has become especially challenging and that trend is expected to continue. The Doctors Across New York (DANY) physician loan repayment program was designed to address that challenge. HANYS embraced that program as one useful tool to address the retention and recruitment problem. However, the state created eligibility criteria and an application process for these grants that creates roadblocks to the program's usage and undermines its potential effectiveness. The recently enacted state budget removes the previous requirement for a competitive bid or request for proposal process and creates a work group to develop a streamlined application process. In addition, it provides for DANY applications to be accepted on a continuous basis, for DOH to provide technical assistance in application completion, and a 30-day turnaround time for proposals.

HANYS' RECOMMENDATION

- DOH should quickly embrace this new flexibility and responsibility and should create a simple, effective, and successful DANY program, based on input from various stakeholders.
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Reduce Survey Duplication

Duplication of inspection activities performed by state agencies and national accrediting organizations is costly to the state and to providers. In the mid-1990s, DOH entered an agreement with the lead national hospital accrediting organization to eliminate duplication of most hospital inspections through an information-sharing relationship between the parties. However, the Wadsworth Laboratories division of DOH chose not to be a party to that relationship and continues to perform duplicate inspections, using the same federal standards that the national accrediting organizations must use. A similar circumstance exists with the Office of Mental Health (OMH) and Office of Alcoholism and Substance Abuse Services (OASAS) inspections conducted for psychiatric and substance abuse services provided by general hospitals that are fully accredited by national organizations.

HANYS' RECOMMENDATIONS

- Wadsworth Laboratories division of DOH should accept accreditation in place of conducting its own inspections and proficiency testing.
 - OMH and OASAS must accept accreditation in place of duplicative state surveys for all psychiatric and substance abuse services provided by general hospitals.
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Allow the Use of Standing Orders

The use of standing orders (i.e., treatment protocols that can be immediately initiated by a registered nurse without a patient-specific medical order) is prohibited in New York State except for a limited set of circumstances involving immunizations. The federal government is in the process of amending the Medicare Conditions of Participation to enable the use of standing orders, especially in emergency circumstances. There are standard, recognized protocols for immediately initiating treatment for patients arriving in an emergency department for asthma attacks, heart attacks, and strokes. However, in New York State, a registered nurse is prohibited from initiating treatment until a patient-specific medical order is written (except with regard to certain specific immunizations) because of limitations in the current Nurse Practice Act. Outdated scope of practice restrictions in New York State are not consistent with current national standards and impede delivery system efficiency. Authority to develop regulations to enable this practice exists in State Education Law Section 6909.

HANYS' RECOMMENDATION

- SED should expand authority of registered nurses to implement standing orders consistent with federal standards.
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Develop Consistent Federal and State Quality Standards

Medicare has defined circumstances (i.e., complications) for which it will not reimburse providers. New York State developed a similar process. However, the state and federal conditions for non-payment differ. Hospitals treat patient medical conditions based on patient need. The state should base its non-payment rules on one consistent set of federal standards, where feasible.

HANYS' RECOMMENDATION

- The state should align its policies and payment procedures with federal standards.
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Behavioral Health

COORDINATION AMONG BEHAVIORAL HEALTH AGENCIES AND BETWEEN DOH AND BEHAVIORAL HEALTH AGENCIES

There is significant duplication of regulations between OMH, OASAS, and DOH. Many of the regulations have different requirements depending on the agency licensing the program, and for hospitals that operate several types of programs, compliance with the different regulations becomes extremely burdensome.

Both OMH and OASAS recently promulgated separate ambulatory patient group outpatient clinic reform regulations that differ in terms of how care is to be provided. In an era when care coordination is sought and the ability to provide services in multiple locations is essential, having separate, very prescriptive, regulations is inefficient and problematic for providers.

OMH's restraint and seclusion regulations differ from those of the Centers for Medicare and Medicaid Services (CMS), The Joint Commission (TJC), and DOH. The differences relate to the staff who are authorized to order a restraint and the amount of observation time required to continue a restraint or seclusion.

Confidentiality laws are also different between the agencies. While DOH and OMH refer to federal Health Insurance Portability and Accountability Act (HIPAA) standards, OASAS requires far more prescriptive regulations that require patient sign-off for sharing of records. This may be extremely difficult to obtain when a patient enters a hospital chemically dependent and needing immediate care.

HANYS' RECOMMENDATION

- To ensure consistency among all federal and state agencies, requirements such as those noted above should be made consistent throughout all licensed program types. HANYS also recommends that the Governor's Office establish a multi-agency workgroup, with health care provider participation, and charge this group with identifying duplicative and/or inconsistent regulatory requirements. The goal should be to standardize agency requirements and make them consistent with requirements set forth by national oversight organizations such as CMS and TJC.
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PHYSICIAN ASSISTANTS IN MENTAL HEALTH ED

New York State Mental Hygiene Law requires that patients can only be admitted based on examination by a physician who determines that the patient qualifies for admission. OMH and Mental Hygiene Legal Services insist that the physician must do the examination. This standard is inconsistent with DOH requirements regarding the practice of physician assistants (PAs) who legitimately practice as “physician extenders,” particularly in areas of the state experiencing physician shortages. The law does not allow a PA in an ED to examine the patient and then review the matter with a physician for decision and physician signature. Although DOH acknowledges that a PA is considered a dependent practitioner working under the supervision of a licensed physician, the OMH regulation has not kept pace with modern practices and limits the use of PAs in an ED.

HANYS' RECOMMENDATION

- The Mental Hygiene Law and others that refer to physicians providing care should be reinterpreted or updated to include PAs where appropriate, and be consistent with DOH requirements governing Article 28 hospital operations.
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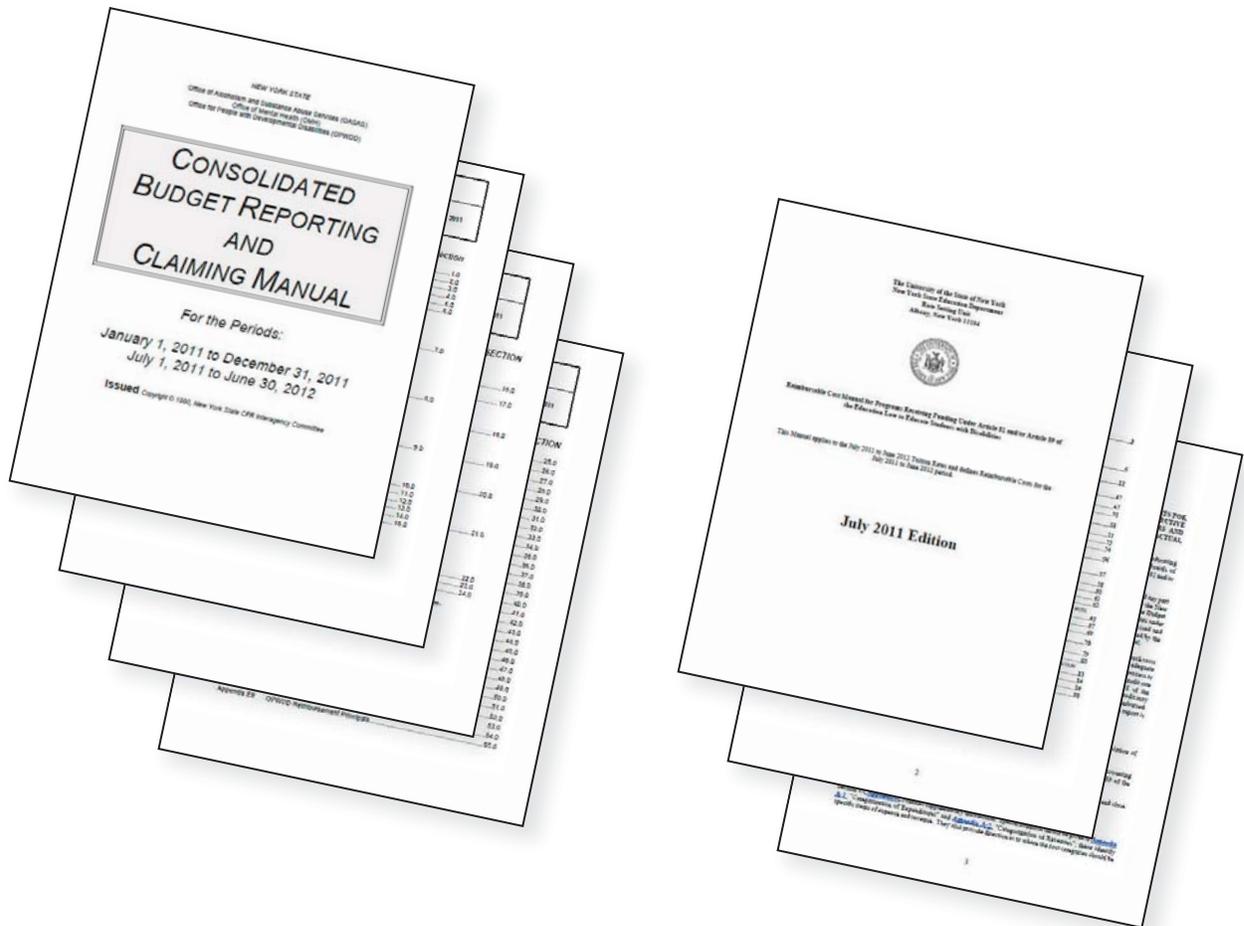


DUPLICATIVE FISCAL REPORTING TO OMH

Hospitals are required to complete an Institutional Cost Report (ICR) each year to report on finances for the entire facility. In addition, Article 28 hospitals with jointly licensed Article 31 programs are required to complete a Consolidated Budget Report (CBR) and Consolidated Fiscal Report (CFR) for OMH. The information is essentially the same and, in fact, when OMH is looking to review Article 28 financial information, OMH uses the ICR as the most accurate and up-to-date information. Therefore, use of CBR and CFR is redundant and unnecessary.

HANYS' RECOMMENDATION

- Article 28 hospitals should be exempt from requirements to complete redundant OMH facility cost reports (CBR and CFR).



Office of Medicaid Inspector General (OMIG)

DISQUALIFIED INDIVIDUALS

When an individual or entity is excluded from the Medicare and Medicaid program, a provider cannot bill these programs for services rendered by the individual. To keep the provider community updated, federal and state Web sites maintain lists of excluded individuals and entities. It is each provider's responsibility to check exclusion lists to determine if any employees, vendors, or associates have been excluded.

There are no federal or state laws or regulations dictating how often providers must check these lists. Nonetheless, in the April 2010 Medicaid Update, OMIG announced that providers must check these lists "monthly, at a minimum."

This requirement, imposed wholly outside the requirements of the State Administrative Procedures Act, affects every entity providing items and services to Medicaid recipients, from the largest academic centers to isolated rural clinics. For providers of all kinds and sizes, OMIG's requirement is burdensome, costly, and a diversion of scarce human resources. No other state in the country has a similar requirement.

When provider agencies commit acts warranting strong intervention by enforcement agencies, they often must agree to comply with demanding Corporate Integrity Agreements (CIAs). These CIAs are published by the federal enforcement agency, the Office of Inspector General (OIG). CIAs almost universally require periodic checking of exclusion lists. Yet, even for providers with acknowledged serious compliance issues, the federal agency demands checking exclusion lists every six months or once per year, not once per month. To our knowledge, no CIA has ever imposed a "monthly at a minimum" requirement.

HANYS' RECOMMENDATION

- OMIG should withdraw the monthly exclusion list-checking requirement. Checking exclusion lists every six months would be a more reasonable approach.
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Reporting Requirements

Health care facilities must report myriad medical occurrences and observations to different sections and databases within DOH. Many of these reporting requirements are evident in their usefulness, such as tracking communicable diseases, reporting suspected cases of child abuse, or keeping a registry of childhood immunizations. For other requirements, providers take time and effort to provide data, yet never share in the results or best practices derived from the data. In addition, some of the same data elements are reported to separate reporting systems.

HANYS' RECOMMENDATION

- The state databases should intersect so that the same elements are only reported once and shared among systems. HANYS recommends the Governor's office establish a work group comprised of DOH and industry representatives to identify these areas of duplication and report back within a six-month period with a plan to eliminate duplicate and non-essential reporting requirements.

COMMUNITY SERVICE PLANS

New York State requires all voluntary, not-for-profit hospitals to submit to DOH an annual Community Service Plan containing an overview of a hospital's community benefit services and programs. In 2010, the Internal Revenue Service required hospitals to list and quantify the community health services they provide on a new Schedule H to Form 990.

HANYS' RECOMMENDATION

- To avoid duplication of community health outreach, education, and prevention reporting, DOH should use the information contained within Form 990, Schedule H to satisfy its needs for community benefit reporting.
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Rural Health

DIAGNOSTIC IMAGING

Existing regulations allow for ED coverage by PAs and nurse practitioners (NPs) if annual ED visit volume is less than 15,000. Providing this flexibility for small community hospitals is critically important, especially in today's environment. However, current DOH requirements for administration of contrast media in the performance of diagnostic scanning procedures require the presence of a physician.

Because of this conflicting staffing standard, valuable diagnostic scans may not be maximally performed in smaller EDs, leading to potentially poorer outcomes for rural residents. Contrast media use in certain procedures provide more definitive, better results. The main reason for the requirement that a physician be present during the use of contrast media is to be available to treat possible adverse reactions. However, there is little risk of an adverse reaction to media agents in use today.

Moreover, similar adverse reactions occurring in the community are routinely treated in EDs. PAs and NPs covering EDs in rural areas are well-versed in responding to such emergencies.

HANYS' RECOMMENDATION

- Eliminate the requirement that a physician be present for contrast media use for hospitals where DOH regulations recognize that ED coverage by PAs and NPs is appropriate.
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PRIMARY CARE HOSPITALS

Current regulations for primary care hospitals, a distinct DOH hospital licensure category intended to be consistent with Medicare Critical Access Hospital (CAH) designation, need updating. These regulations have been in place for well over a decade and have not kept pace with changes in federal CAH rules. An overhaul of Part 407 Primary Care Hospitals—Minimum Standards is long overdue.

HANYS' RECOMMENDATION

- Primary care hospital regulations should be modified to reflect the contents of federal CAH Conditions of Participation, as they represent a distinct subset of hospitals intended as rural safety net facilities.
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Conclusion

New York's health care providers are committed to creating a more patient-centered and efficient health care system, focused on coordinated care delivery, improved health status, and better patient outcomes.

At a time when both federal and state governments are supporting payment reform to reconfigure the institutional-based health care delivery system, outdated state rules are standing in the way of desired change.

HANYS has identified many ways New York State can streamline myriad rules and regulations to decrease the financial and regulatory burden on providers and devote more resources to patient care.

HANYS' recommendations would decrease the number of regulations that no longer reflect current medical practice and lead to the elimination of duplication of efforts that take time away from patient care. HANYS also offers a number of ways in which health care can be streamlined with more appropriate models of care that are better for patients and more cost-effective.

HANYS urges New York State to act now to untangle the red tape that stifles health care providers' mission to provide quality care to all, and hampers needed reform.

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