HOW DUPLICATIVE, UNNECESSARY, AND OUTDATED REGULATIONS RESTRICT HOSPITAL EFFICIENCY AND DIMINISH PATIENT CARE

For nearly every hour a nurse provides direct care to a patient in a New York State hospital, another hour of paperwork must be completed to comply with hundreds of state and federal rules and regulations.

Many of these rules and regulations are essential to ensure accountability and quality care. However, a large and growing number are simply outdated, unnecessary, or duplicative, resulting in tens of thousands of hours of lost staff time that would otherwise be committed to patient care.

This tangle of rules is one of the most significant barriers to improving patient care, increasing job satisfaction for clinical staff, and reducing operating expenses.

If we are serious about health care reform, we must improve our state’s regulatory structure.
EXECUTIVE SUMMARY

Many rules and regulations initially implemented to protect patients are instead wasting valuable resources and thereby threatening or diminishing patient care services.

*Tangled Up in Rules* identifies the most serious regulatory problems and recommends actions to modernize and rationalize the regulatory environment. This will free health care providers from the restrictive and costly tangle of unnecessary rules and regulations that take time away from direct patient care.

Regulatory reform provides New York State with a real opportunity to improve health care without adding costs to the system.

This document covers the following issues:

**CON REFORM:** Unnecessary delays in Certificate of Need (CON) reviews are caused by cumbersome paperwork, lack of timely response to applicant inquiries, and regulations that have not kept pace with changing models of care.

**HEALTH PLANNING/NEW MODELS OF CARE:** System redesign and payment reform can help to provide better care for patients in the most appropriate setting, but regulations must be revised or eliminated to better reflect changes in models of care and new technologies.

**MEDICAL MALPRACTICE REFORM:** Malpractice rates are skyrocketing and the resulting impact is severe: physicians are leaving New York State to practice elsewhere or are choosing to stop performing certain services, hospitals have reduced or eliminated services, and patients are losing access to care. Other states offer proven examples of effective programs that have reformed medical malpractice and reduced costs.

**STANDARDIZATION/CERTIFICATION/REDUCING SURVEY DUPLICATION:** Providers undergo duplicative surveys, must comply with inconsistent requirements of multiple agencies, and experience wide variation among oversight agency staff in interpreting existing policies and regulations.

**CREDENTIALING:** This onerous process imposes burdens on hospitals that do not have an adequate number of practitioners in their communities and forces providers to contract with professional service vendors.
REPORTING REQUIREMENTS: Many of these are unnecessary or duplicative and are not clearly linked to a current public policy objective or quality improvement initiative.

WORKFORCE/SCOPE OF PRACTICE: With severe workforce shortages, nationally recognized models of care, and advances in technology, practice requirements for some health professionals are impeding the delivery of care.

OFFICE OF THE MEDICAID INSPECTOR GENERAL: Excessive demands and lack of clarity in the interpretation of many regulations present serious issues for providers.

CLINICAL INTEGRATION: The state should enable greater collaboration among health care providers, focused on quality improvement and implementing and monitoring clinical protocols.

MANAGED CARE: Without proper oversight of health plan networks, the health needs of enrollees are in jeopardy.

FINANCE: Many regulatory requirements negatively affect, and at times impede, hospitals’ ability to obtain reimbursement and needed capital.

RURAL HEALTH CARE: To enable greater efficiencies in the health care system, the state should alleviate providers excessive fiscal and regulatory burdens.
CON REFORM

UPDATING AND STREAMLINING THE SYSTEM

After years of logjam in the Certificate of Need process, DOH has recently focused on revamping CON regulations and developing an electronic application to reduce unnecessary paperwork and improve responsiveness. But the changes are not enough and are not coming quickly enough to make the CON process work for all stakeholders.

HANYS has long supported streamlining the process by raising the cost thresholds that trigger review. However, it now takes considerably longer to process the less intensive administrative reviews—and proposed reforms will only add to the number of projects that fall into this category, thereby adding to a growing backlog.

According to the 2008 annual report of the State Hospital Review and Planning Council (SHRPC), the median timeframe for processing an application requiring full review (and SHRPC approval) was 148 days, while the median time required for approval (with contingencies) of the less intensive administrative review lasted 210 days. Two years earlier, for applications assessed in 2006, full reviews took a median of 229 days, while administrative reviews took 175 days.

The average timeframe for processing routine, administrative review applications is indefensible. Efforts to reduce the levels of review needed for less costly projects have only shifted the backlog, creating a system where simpler, more routine projects that are almost always approved in the end are now held longer in the system.

HANYS is pleased that regulatory reform is already under review to move more routine projects, such as magnetic resonance imaging and computerized tomography scanners, out of the administrative review category, and we support quick adoption of these measures. We also recommend time limits for the architectural reviews that would still be necessary for these routine services.

Many HANYS members have established good working relationships with CON review staff who are helpful and provide necessary guidance. Unfortunately, other applicants report a byzantine system with conflicting rules between the regional and central offices, and among various review agencies. Providers straddling two DOH regions may have different sets of
rules, depending on the location of their service providers. This leads to delays in opening programs, depriving patients of access to new services and, ultimately, adds costs to the health care system.

HANYS’ RECOMMENDATIONS

HANYS supports reform that will reduce the number and type of applications requiring review.

- HANYS urges a more aggressive and resource-conscious review of the CON process to determine how best to use limited DOH staff resources and provide the most effective state oversight to enable safe and affordable health care across the state. We support reform that will reduce the number and type of applications requiring review. This is particularly essential for those services that have become routine care, as well as those areas where unlicensed operators may freely develop the same services outside the purview of state regulation.

- The only clear way to improve the timeliness of the process is to substantially reduce the number of applications requiring review. The system should be designed so that the volume of CON submissions is commensurate with available DOH resources to process that volume:
  - full reviews should be completed within 120 days; and
  - administrative reviews should be completed within 60 days.

- This should be accomplished by raising dollar thresholds, and employing other categorical exclusions—clinical and non-clinical. Identifying categories of projects that are universally approved is a good place to start. DOH can continue to track projects in which there is patient safety or architectural and engineering interest by using the “notice only” option. The goal should be to scale the criteria for administrative reviews such that the process is completed within a 60-day period.
HEALTH PLANNING/NEW MODELS OF CARE

System redesign and payment reform can help New York's hospitals and health systems provide better care for patients in the most appropriate setting. Below are two examples of innovative care models that should be embraced in New York.

IMPROVING TRANSITIONS TO CARE THROUGH TRANSITIONAL CARE UNITS (TCUs)

HANYS continues to advocate for expansion of transitional care units. A demonstration project, authorized by the State Legislature in 2005, has allowed five participating hospitals to provide specialized post-acute services to elderly patients in a dedicated unit, and receive a Medicare per diem reimbursement rate, based on the Skilled Nursing Facility Prospective Payment System. Demonstration project authorization concludes in April 2010.

TCU care addresses the medical problems that may persist following a patient's acute care stay. Examples include follow-up care for hospitalization of acute heart and lung conditions, tracheotomies, extensive wounds difficult to heal due to complications from chronic diseases such as diabetes or vascular insufficiency, and unstable recoveries following major surgery. Currently in New York State, hospitals that are not part of the demonstration and are unable to discharge a patient to an appropriate post-acute setting often care for patients in their inpatient units, when they require specialized care beyond the length of their traditional Medicare stay. In these cases, hospitals receive no payment for the services. This demonstration draws more Medicare dollars to New York to reimburse hospitals for these longer stay patients.

Early results show that TCUs can improve access to care, quality, and patient outcomes, and decrease hospitalizations, thereby providing value in the provision of post-acute care for elderly patients. A preliminary report evaluating the 2005 demonstration, released in 2008, stated, “TCUs may facilitate a smooth, more timely and appropriate transition from the acute care setting to the final discharge outlet, decreasing the likelihood of costly re-hospitalization related to acute episodic illnesses.”

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Source: 2008 State DOH Report
Emergency departments (EDs) in many of New York’s hospitals are increasingly overwhelmed and looking for new strategies and tools to better manage the treatment and flow of patients in the safest and most cost-effective way. One tool hospitals have is a special unit within an ED for patients awaiting the results of diagnostic tests or further evaluation to determine whether they need admission to an inpatient unit. These services allow patients to be moved out of the crowded ED while their condition continues to be evaluated, without rushing the decision on whether there is a need for admission to the inpatient unit.

These special beds, called observation services, are a distinct set of services and are reimbursable by Medicare and many private payers. But New York’s Medicaid program does not recognize observation services and, therefore, has no special payment for them.

The American College of Emergency Physicians recognizes observation services as a “best practice” and urges hospitals to create a dedicated place for patients undergoing short-term treatment, assessment, or other care for a limited period.

**HANYS’ RECOMMENDATION**

- With the successful conclusion of the demonstration period, the Department of Health (DOH) should “grandfather” the five existing TCU services and allow other hospitals to apply for such services though the CON process.

**OBSERVATION SERVICES**

- DOH should formally recognize observation services, where appropriate, and create a Medicaid payment rate for these services. Currently, through a DOH waiver process, a small number of hospitals in the state operate these units. The experience derived from these demonstration projects can help guide future design and payment systems for these services.
MEDICAL MALPRACTICE REFORM

The explosive growth in medical malpractice insurance premiums is exerting immense fiscal pressure on physicians and hospitals, and negatively affecting patient care. Physician malpractice rates skyrocketed 14% in 2007 alone, and annual premiums are commonly as high as $200,000 or more for a single physician. Hospitals in New York State alone spent $1.4 billion on malpractice coverage in 2006. Exorbitant premiums are straining the ability of doctors and hospitals to meet basic operational demands. These levels are simply unsustainable and are an obstacle to any efforts to reduce the escalating cost of health care.

High premium costs are resulting in “physician flight” as doctors are driven out of such high-need specialties as obstetrics/gynecology, neurosurgery, and emergency care. The physician shortage is now a serious problem in many areas of the state, and recruitment of new physicians into New York is a discouraging challenge.

The fact is, the current medical malpractice system is terribly broken—it is harming, not helping, health care in New York State. The cost of insurance and the cost of defensive medicine have created a demand for doctors that cannot be met, a demand for critically needed services that our health system cannot fulfill, and rapidly increasing costs that cannot be sustained. Yet, medical liability claims, jury awards, and settlements are all increasing, without regard to the clear lessons from other states about available, effective medical malpractice reform.

We cannot continue to sustain inaction to reform the system, particularly given the fiscal realities of the state budget. It is far more effective to take the millions of dollars wasted on an irrational and grossly ineffective malpractice system and instead spend them on critically needed areas, such as adding or expanding essential services, addressing staffing shortages, and investing in health information and other technologies to improve care.
New York State should:

- adopt a medical indemnity fund to provide an alternative financing mechanism for specific, high-cost cases involving neurological impairment;
- implement optional medical tribunals (e.g., specialty courts);
- implement and promote a “sorry works” program to encourage physician-patient communication without fear of reprisals;
- enact a cap on non-economic damages in malpractice lawsuits.

President Obama has provided $25 million over three years to support state medical malpractice reform demonstration programs. While not a significant amount of money (a maximum of $3 million per state), it is nevertheless a stimulant for state action. HANYS urges that the state consider supplementing the federal funds to enable a broader program.

Physician malpractice rates skyrocketed 14% in 2007 alone.
STANDARDIZATION/CERTIFICATION/REDUCING SURVEY DUPLICATION

STANDARDIZATION

In addition to myriad quality of care standards, providers must also comply with structural, architectural, life safety, and other physical plant requirements. These often vary among oversight agencies. The differing standards applied by DOH, Centers for Medicare and Medicaid Services (CMS), Office of Mental Health (OMH), and The Joint Commission (TJC) challenge even the most aggressive compliance programs to meet the latest requirements. Providers experience these challenges both through the CON process and during surveillance activities, where inspectors from different agencies may issue conflicting findings for the same conditions.

HANYS' RECOMMENDATIONS

- HANYS recognizes that DOH only has direct control over the standards it applies. We recommend that DOH adapt its standards to conform with national oversight organizations’ standards, where possible, to begin to establish consistency in oversight activities at all levels of government.

- DOH should adopt CMS’ policy with respect to “deeming” compliance with a national oversight organization’s standards to be equivalent to compliance with New York State standards. Relief in this area makes sense both for providers and for the agencies involved.

LABORATORY SURVEYS

To succeed in this severe economic environment, New York’s hospitals must identify opportunities to improve efficiency and reduce costs, without compromising quality health care. One area that has come under scrutiny is accreditation, and several of our members have raised concerns about the duplicate laboratory survey requirements of TJC and DOH. Survey duplication is disruptive to operations and must be eliminated.

DOH conducts a rigorous survey of hospital laboratory services. This state survey mandate is in addition to the laboratory survey requirement by TJC as part of its hospital accreditation. The state survey addresses the same essential components as TJC’s survey. In fact, the DOH survey goes beyond TJC’s review, providing a detailed evaluation of laboratory operations that includes the use of tracers.
This duplication simply makes no sense, especially in the current fiscal environment. Undergoing two independent and roughly equivalent laboratory surveys wastes scarce material and human resources, and imposes considerable expense and administrative burden on hospitals. Moreover, the effort can inappropriately divert hospital resources and attention away from other priorities critical to patient safety.

HANYS’ RECOMMENDATION

- HANYS is coordinating discussions with DOH and TJC to develop a collaborative survey process where both organizations would conduct their surveys concurrently and ultimately rely on each other, rather than duplicate their efforts. A pilot of this new process is being planned. HANYS urges the process to be expedited and a single collaborative survey process be implemented.

REGULATORY INTERPRETATION

In addition to conflicting standards among agencies, there may be varying interpretations of the same regulations and standards within an agency.

CMS publishes interpretive guidelines, sets forth protocols for state agencies conducting Medicare surveys, and has mandated surveyor training. TJC also sets forth survey protocols and extensively trains its surveyors pursuant to those protocols.
COORDINATION AMONG DOH AND BEHAVIORAL HEALTH AGENCIES

There is significant duplication of regulations between DOH and behavioral health agencies, and some regulations have different requirements depending on the agency licensing the program. For example, the restraint and seclusion regulations are the same for CMS, TJC, and DOH, yet different for OMH. The differences are in the staff who are authorized to order a restraint and the amount of observation time required to continue a restraint or seclusion.

In addition, the patient rights regulations differ between DOH, OMH, and the Office of Alcoholism and Substance Abuse Services (OASAS). Acute general hospitals that operate a range of substance abuse and/or behavioral health services are subject to licensures and regulatory oversight by multiple state agencies, including DOH, OMH, OASAS, and/or the Office of Mental Retardation and Developmental Disabilities (OMRDD).

HANYS' RECOMMENDATIONS

- State agencies should take steps to develop and publish interpretations of state regulations, and develop standardized survey protocols to be shared publicly. Since state hospital code requirements are to a large degree modeled after Medicare Conditions of Participation requirements, standardizing state and federal interpretations will lead to better overall compliance.

- In addition, to validate the effectiveness of an effort to reduce variability in the survey process and to ensure ongoing consistency, survey activities should be subject to internal and external periodic evaluations.

To ensure consistency among all federal and state agencies, requirements should be made consistent throughout all licensed program types.

HANYS' RECOMMENDATIONS

- To ensure consistency among all federal and state agencies, requirements such as those noted above should be made consistent throughout all licensed program types.

- The Governor’s office should establish a multi-agency workgroup, with industry participation, and charge this group to undertake a “Lean” or “Six Sigma-like” effort to identify duplication and/or inconsistent regulatory requirements. The workgroup should be given a set timeframe for developing a plan for correcting problems. A specific goal should be to standardize agency requirements and make them consistent with requirements set forth by national oversight organizations such as CMS and TJC.
HOSPITAL INPATIENT PSYCHIATRIC UNIT SURVEYS

Article 28 hospitals that operate inpatient psychiatric units are subject to oversight by DOH, OMH, and TJC. HANYS has been working with OMH and TJC for some time to develop a survey process that would meet OMH and TJC responsibilities, but would be conducted by a lead agency (TJC) on behalf of both organizations. The relationship would be similar to the routine survey delegation from DOH to TJC for general hospital surveys that have been in place for more than a decade. A pilot of this new survey relationship between OMH and TJC is underway.

HANYS’ RECOMMENDATION

- The pilot for this new survey process should proceed rapidly and OMH should enter into a survey relationship with TJC beginning January 1, 2010.

MEDICAL RESIDENT WORKING HOURS SURVEYS

DOH annually surveys hospitals where residents are employed to determine levels of compliance with working hour limitations. These surveys include document reviews and detailed direct interviews with residents, which take them away from their patient care duties. Findings by DOH in recent years indicate nearly universal compliance with these regulations.

The American College of Graduate Medical Education (ACGME) standards for resident working hour limitations are nearly identical to DOH’s. Hospitals must comply with ACGME standards for their residency programs to be accredited.

HANYS’ RECOMMENDATION

- DOH and ACGME should develop a single survey process. In addition, hospitals should not be surveyed for compliance with these rules more frequently than once every three years.
CREDENTIALING

The practitioner credentialing process imposes a substantial administrative burden on hospitals that do not have an adequate number of practitioners in their communities and contract with professional service vendors to provide needed coverage. These contracted service vendors in turn may have hundreds of other contractual relationships. Under current state rules, contracting with organizations of this nature necessitates that hospitals conduct credentialing reviews of physicians, in some cases hundreds, who work as contracted professionals at numerous other hospitals. It is common practice for community hospitals to employ multiple staff to conduct these tremendously burdensome and costly reviews.

DOH has helped to lessen this burden somewhat through interpretation, allowing hospitals to “contract with an outside entity to carry out all or part of the professional application/review and credentialing process.” DOH further stated, “A facility may designate, by contract, an agent to receive and collect credentialing information, perform all required verification activities, and act on behalf of the facility for credentialing purposes.”

As the physician shortage in many areas of the state becomes more severe, it is probable that hospital reliance on professional service vendors will continue to grow. These organizations provide services throughout the country and the world. With this magnitude of potential exposure, they must follow a very high standard for the quality of physicians they employ.

HANYS’ RECOMMENDATION

- DOH should deem the credentialing process implemented by physician staffing organizations equivalent with credentialing responsibilities required of Article 28-licensed hospitals. This would allow hospitals in New York State to contract for the professional service and to designate the service vendor to act as the agent of the hospital to carry out credentialing responsibilities. Such deeming would provide substantial process and cost relief without harming quality.
REVISIT 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.

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 workgroup 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.

NYPORTS

New York Patient Occurrence Reporting and Tracking System (NYPORTS) reporting obligations have expanded well beyond statutorily required reporting, and some requirements overlap with those of other agencies.

- Eliminate any reporting category not clearly required by statute. By doing so, the burden on providers will be lessened, and the information that is collected will be more consistent and better utilized.

- Where possible, NYPORTS statutory reporting categories should be defined using such current reporting requirements as the CMS hospital-acquired conditions. Standardized definitions will reduce duplicative, misaligned reporting obligations, and will result in more accurate and consistent reporting.

- The Governor’s office should form a multi-agency workgroup, with industry representatives, to conduct a comprehensive review of all state quality data reporting requirements, beginning with DOH, with the goal of eliminating any that no longer serve a clear purpose or have value commensurate with the effort needed to continue reporting the elements.
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 will require hospitals to list and quantify on a new Schedule H to Form 990 the community health services they provide.

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.
WORKFORCE/SCOPE OF PRACTICE

TELEMEDICINE

The state’s Medicaid program has recently allowed for coverage of specialist consultations in the emergency room and inpatient areas of the hospital, which shows promise in improving care of chronic conditions, reducing readmissions, and avoiding travel to distant locations for care. The coverage rules should be expanded to allow payment for telemedicine coverage in outpatient clinics and other settings such as nursing homes, and expansion of the demonstration for home care services.

While telemedicine is not appropriate for all types of care, it can substitute for disruptive travel for patients or nursing home residents who have impaired mobility or lack of access to qualified specialists near their homes. A recent grant-funded telemedicine project showed improvement among nursing home residents with Parkinson’s disease who were able to undergo remote evaluation by neurologists rather than having to travel for their care.

Because of a lack of practitioner candidates and geographic location, many hospitals simply will not be able to attract a full complement of physicians to their areas and will have to consider alternatives to ensure that most geographically isolated patients have access to appropriate care. Telemedicine is one option that can be used to address this gap.

HANYS’ RECOMMENDATION

- New York should significantly expand the settings where services provided via telemedicine are reimbursed through Medicaid, including long-term care settings and outpatient clinics.

RATIO REPORTING BILL

Despite strong opposition by HANYS, New York Organization of Nurse Executives, the allied associations, and members, Governor Paterson has signed legislation (A.1752-A, Gottfried/S. 3527, Duane) requiring hospitals, nursing homes, and clinics to report on nurse staffing ratios and certain adverse events. The bill will go into effect in mid-March 2010 and DOH will soon begin its associated regulatory process. This bill is outdated and does not take into account initiatives put into place since it was first proposed in 1997, including the hospital-acquired infection reporting law of 2005.
The bill requires the reporting of various quality-related measures, most of which are now redundant because of existing reporting requirements that involve teams of caregivers that are not limited just to nurses.

It also promotes staffing and other comparisons among facilities where comparisons are not appropriate, and when there are no standardized measurement tools, and would therefore be difficult to interpret in a meaningful way. Staffing is determined by a host of complex, interrelated factors that vary across facilities.

**HANYS’ RECOMMENDATION**

- DOH should ensure the development of a reporting mechanism that minimizes the new burden placed on providers. HANYS volunteers to work with DOH to ensure only the collection of relevant and meaningful quality-related information that will not duplicate existing reporting or create further confusion.

**DOCTORS ACROSS NEW YORK**

While this program cannot meet the shortage needs for the entire state, it can make a significant contribution if funded appropriately and implemented in such a way that removes barriers to recruitment. Unfortunately, in the initial round of funding under this program, narrowly defined eligibility requirements and lack of flexibility caused by the procurement process have led to limited success in attracting new physicians to New York State.

**HANYS’ RECOMMENDATIONS**

- DOH has given awardees only six months to identify physicians to participate, but a typical recruitment can take as long as 18 months. DOH must allow no-cost time extensions for grant awardees to give members time to recruit physicians.

- Eliminate the eligibility timeframe for when a doctor completed his or her residency. Currently, hospitals may only recruit physicians up to five years post-residency.

- Allow flexibility in recruitment for other needed specialties. Applicants were permitted to submit two applications for specifically named specialties in need. Because of the length and complexity of the recruitment process, several hospitals have been unable to find the identified specialist within the designated timeframe, but have recruited other needed specialists who cannot be covered because the specialty was not explicitly named in the award.
Currently, physicians eligible for awards must have a New York connection (e.g., resident). This should be a preferred qualification, but not a mandate.

EMS IN THE ED

Emergency medical personnel’s ability to practice is defined by location under current interpretation of the Public Health Law by DOH and scope of practice by the State Education Department (SED). This narrow view technically precludes Emergency Medical Services (EMS) workers from helping transition their patients to the care of the ED staff, because they may not provide care to patients after they cross the threshold of the hospital.

This is not a prudent or necessary limitation, particularly in EDs during periods of high demand. In fact, it generally takes some time for EMS personnel to hand over a patient and for hospital staff to be able to accept that patient. During this transition period, which occurs in the ED, the patient must still be attended by EMS personnel.

HANYS’ RECOMMENDATION

- DOH should use flexibility within its workforce demonstration authority to allow qualified EMS personnel to provide necessary treatment to emergency patients in hospital EDs as part of an emergency care team. HANYS is prepared to convene a group of members to work with DOH to help define parameters of such a demonstration.

NURSES IN THE ED

State statute requires nurses who staff EDs to have completed one year of clinical experience. With the increased demand experienced by many EDs in the state today, maintaining adequate staffing is challenging.

HANYS’ RECOMMENDATION

- If a hospital determines that a nurse is qualified by training, experience, and demonstrated competence, he or she should be allowed to care for patients in the ED.
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 nursing home certified nurse assistant is defined at the federal level as a Medicare Condition of Participation.

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.

LICENSING REQUIREMENTS FOR CERTAIN HEALTH CARE PROFESSIONALS

Several professions licensed through 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.
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.
The Office of the Medicaid Inspector General (OMIG) is building a track record of excessive demands for documents, unsupported interpretations of rules, and unjustified recoupments of funds from providers.

OMIG’s auditing process often commences with data searches using inaccurate or unfounded criteria. These searches generate lists of hundreds, if not thousands, of claims that OMIG requires providers to justify. Satisfactory justification, according to OMIG, requires retrieving, reviewing, and reproducing voluminous years-old records. To comply with such demands, providers not only divert staff from important responsibilities, but retain agency personnel at a premium price. Intense record retrieval disrupts the day-to-day operations of providers and entails significant expense. These difficulties are multiplied when OMIG conducts several audits simultaneously or consecutively on the same provider.

Providers are witnessing an unparalleled expansion by OMIG of regulatory interpretation. For example, OMIG believes that payment is conditioned on 100% compliance with Conditions of Participation, such as a requirement that an employee undergo an annual physical exam or that a document be signed within a specified period. Rules intended to assure appropriate provider operations are applied to justify payment for services. Citing references indicating that a provider should operate in accordance with all applicable rules, OMIG elevates the standard to mean that infractions such as a missed documentation deadline or use of an incorrect code number justify demands for repayment.

In its workplans and public statements, OMIG cites compliance with mandatory reporting laws as a payment requirement, yet fails to explain its criteria for determining “compliance.” Similarly, OMIG cites adherence with credentialing regulations as a payment standard without justifying its view of the relationship between the two.

When an incorrect code is entered on a claim, the recovery is the full amount of the payment. If an employee provides services beyond his or her annual physical due date, the employee is “unqualified,” meaning the provider should be paid nothing for the service. OMIG’s position is that if a provider does not adhere to a regulatory provision, particularly documentation rules, the entire amount of the claim should be disallowed.
In the private, third-party payer sector, managed care company tactics that use “administrative denials” to reject payment for medically necessary, covered services are universally criticized. Privately insured individuals will not stand for such practices. Medicaid beneficiaries deserve the same public advocacy—medically necessary services should be reimbursed.

**HANYS’ RECOMMENDATIONS**

- The purpose of Medicaid is to pay providers the cost of delivering necessary, adequate, and appropriate care. Yet, the need for and appropriateness of care that is in fact delivered is frequently ignored in the quest to deny payment. Recoveries are often disproportionate to the severity of the infraction and result in no payment for services rendered, even in instances where the propriety of care is not in question. Medical necessity should be the paramount criterion for payment.

- Establish consistency in interpretation of reimbursement regulations between OMIG and the rest of DOH.

- The state should also re-open discussion with CMS regarding fraud/abuse recovery targets contained in the Federal-State Health Reform Partnership (F-SHRP) waiver to receive proper credit for prevention or avoidance efforts on the part of providers and to allow the carryover of savings from one year to the next.

Medical necessity should be the paramount criterion for payment.
CLINICAL INTEGRATION

There is public interest in fostering greater collaboration among health care providers to promote quality improvement, patient safety, and efficiency. By combining resources and collectively developing, implementing, and monitoring clinical protocols or other quality improvement initiatives, providers can deliver higher quality care in a more efficient manner than could be achieved working independently. The recently authorized Adirondack Medical Home Demonstration is one example of the merit of clinical collaboration. The authority in Public Health Law for rural hospitals to engage in collaboration is another representation of the state’s interest.

The promotion of clinical integration initiatives would improve the health status of patients and communities, enhance patient safety, reduce costs, result in high-quality efficient health services, increase the use of electronic medical records and other health information technology, align hospital and physician incentives, create transparency of data and clinical information results, and improve consumer health care decision-making.

To facilitate these collaborations in light of potential federal anti-trust concerns, HANYS has asked for state guidance or a state process to pursue immunity protections, similar to the arrangements that were established for providers who were interested in facility rightsizing under the Commission on Health Care Facilities in the 21st Century (the Berger Commission).

HANYS’ RECOMMENDATION

For providers interested in pursuing clinical integration initiatives, the state should establish a process similar to one developed for Berger Commission collaborations. State-authorized immunity is needed to ensure anti-trust protection to assist with planning, implementation, and operation of clinical integration initiatives, including the collective negotiation of reimbursement rates by health care providers participating in such programs.
MANAGED CARE

OVERSIGHT OF MANAGED CARE PLANS

DOH is solely responsible for reviewing the adequacy of the provider network of each managed care plan at three key points: upon initial licensure, at least once every three years after licensure, and if the managed care plan expands its network. The State Insurance Department (SID) has no statutorily granted responsibility to review networks, establish standards, or assist DOH in these duties.

Without proper oversight of health care networks, the health care needs of enrollees are in jeopardy. The law requires DOH to consider geography, consumer choice, adequacy of the provider network, access to specialty care, cultural and linguistic needs, and timely access to care. It is unclear whether DOH, through its current regulatory responsibility, is able to ensure that managed care plans meet the comprehensive health care needs of their enrollees.

Currently, DOH and SID jointly regulate health insurance. As with network adequacy, DOH has exclusive oversight of certain regulatory functions. SID has oversight of other unique functions, such as agent licensure. In some cases, this separation of powers is logical and necessary. Other times, however, it is cumbersome and can create barriers to ample oversight of this multifaceted industry.

HANYS’ RECOMMENDATIONS

- Review the process used to ensure that each managed care plan offers enrollees a network that meets their health care needs, including clear delineation of roles for DOH and SID. Suggested areas of examination are the timeliness of reviews, standards for review, and feedback mechanisms for enrollees whose health care needs were not met. With a broad review, areas of duplication would be avoided, inconsistencies would be cleared up, roles would be simplified, and lines of leadership would be apparent. At the very least, managed care entities must be subject to the same level of oversight and scrutiny that is applied to institutional providers of care.
The Governor’s office should establish a workgroup composed of DOH, SID, the provider sector, and insurers to review current managed care plan oversight responsibilities of DOH and SID to reduce inconsistencies and duplication, and to enhance coordination.

**BALANCE BILLING**

Many practitioners choose not to participate in managed care insurance plans due to the inadequacy of rates, administrative burdens, and interference in clinical practice. Health plans typically pay non-participating or out-of-network practitioners usual, customary, and reasonable (UCR) rates. Dissatisfied out-of-network practitioners often have no choice but to bill their patients for the difference between the true cost of service and the UCR rate. HANYS is concerned that imposing a statutory or regulatory prohibition on balance billing will exacerbate existing problems. Core issues of inadequate reimbursement would still exist and physician workforce and coverage issues would worsen.

**HANYS’ RECOMMENDATION**

- Prohibiting balance billing would not address the issue of inadequate reimbursement rates. Instead, require health insurers and health maintenance organizations to use an independent source for establishing fair and accurate UCR rates, which reflect geographic differences in costs, and are transparent to the consumer.
FINANCE

REINSTATEMENT OF IDA FINANCING FOR ARTICLE 28 FACILITIES

Hospitals and nursing homes in New York State struggle with aging physical plants and must meet the constant demands of doctors, health care professionals, and patients for high-quality, updated, higher-technology services. Restoration of access to the financing vehicle offered by local Industrial Development Agencies (IDAs) will provide Article 28 facilities with a much-needed lower-cost financing option that will save time and money for health care facilities, the state, and patients. Many otherwise “shovel ready” health care projects have been placed on hold indefinitely since access to IDA financing expired in February 2008.

However, recent attempts to reestablish IDA financing for these facilities have included additional requirements that would make needed capital improvements cost-prohibitive for many facilities.

**HANYS’ RECOMMENDATION**

- IDA financing must be reestablished to allow all not-for-profit, Article 28 facilities access to tax-exempt financing.

CREATE AN EXTERNAL APPEALS PROCESS TO REVIEW MEDICAID CLAIMS DISPUTES

The Medicaid program uses IPRO to review claims for appropriateness of payments made to providers. The number and dollar amount of IPRO claim denials has been increasing. In the state’s external appeals program, patients and providers may select from a number of dispute resolution agents to adjudicate disputes. The state should consider creating an optional external appeals process, similar to what is done with commercial payers. The current process only allows for one level of appeal with IPRO, and IPRO is affirming its own decision, so there appears to be an inherent conflict of interest in the current process. The Medicare program, alternatively, allows for up to five levels of appeals through different review agents.

**HANYS’ RECOMMENDATION**

- The state should permit providers to appeal to alternative dispute resolution agents for the adjudication of payment disputes, or adopt a process similar to the one used by Medicare that allows for multiple levels of review by different entities.
COST REPORTING

Among the many reporting requirements that could be improved to yield more valuable data is the Institutional Cost Report (ICR).

The ICR should be streamlined and clarified, including aligning it better with other state reporting systems, improving the reporting instructions, and eliminating redundancy with the Medicare Cost Report. HANYS appreciates that state officials are pursuing these requests through formation of a workgroup that includes health care representatives.

HANYS’ RECOMMENDATION

CAPITAL FINANCING: STREAMLINING PROCESS FOR OBLIGATED GROUP DEBT

Fifteen years ago, the state expanded opportunities for capital debt financing in a tight credit market by creating a process for approving obligated groups—as a way of elevating the credit rating of previously separate hospitals. Because there was concern about the pooling and pledging of multiple organizations’ assets, the state created a quasi-establishment process for participation in an obligated group, where any participating entity had to meet normal character, competence, and financial feasibility standards. That requirement effectively means that obligated groups have only involved in-state hospitals. It has been impossible to entice hospital systems outside the state with significant corporate assets and complicated multi-state structures (e.g., Ascension, Catholic Health East) to participate in the process with New York affiliates because it would subject their entire corporate enterprise to the burden of New York’s establishment process.

The challenge of the credit markets and difficulty in obtaining debt financing today necessitate a fresh look at this issue. Hospitals in New York that have national affiliations are missing an opportunity to enhance their credit ratings and access less expensive debt if the state would modify its obligated group requirements.

HANYS’ RECOMMENDATIONS

- Requirements for the creation of obligated groups should be revised to allow not-for-profit, multi-state systems to invest capital resources in their New York affiliates.

- The state should consider obligated group participation outside of the hospital establishment process. This approach should also be considered as a simplification for the formation of state-only obligated groups involving existing hospitals.
RATE APPEALS

Currently rate appeals lag in the system for many years.

- **HANYS’ RECOMMENDATION**

  - DOH should contract with an outside entity to eliminate the backlog. Once the cleaning-up exercise is completed, DOH should set a reasonable deadline (90 to 120 days) by which Medicaid appeals for both hospitals and nursing homes must be processed.

TIMELY ISSUANCE OF REIMBURSEMENT RATES

Delays in the issuance of Medicaid rates impedes facilities’ ability to bill properly for services provided.

- **HANYS’ RECOMMENDATION**

  - Medicaid rates should be promulgated within 30 days of their effective date to permit proper facility budgeting. If CMS’ approval is required, the effective date of implementation should incorporate adequate time to secure that approval.

DUPLICATIVE FISCAL REPORTING TO OMH

Hospitals are required to complete an 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).
RURAL HEALTH CARE

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 provides 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 to media agents in use today. However, there is little risk of an adverse reaction.

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.

PHYSICIAN COVERAGE

For hospitals where DOH regulations allow for ED coverage by PAs and NPs, there is a requirement that a physician be able to respond within 20 minutes, if needed. The 20-minute time requirement has become exceedingly difficult to achieve as physician resources in rural areas continue to shrink.

HANYS’ RECOMMENDATION

- The 20-minute response timeframe is arbitrary and outdated. The response timeframe should be extended to a more realistic 30 to 40 minutes. HANYS also supports the use of telemedicine to make an initial assessment as an alternative to requiring the physician to be on-site.
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.
CONCLUSION

With health care costs skyrocketing, limited health care facility and government resources, and the advent of comprehensive health care reform, 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.