

North Carolina



Medical Society

Leadership in Medicine



2016 LEGISLATIVE SUMMARY

“THE NEXT GEN FIX”

HB 287 / S.L. 2016-78

This year, NCMS led a successful effort to ensure NC-based ACOs could continue participating in Medicare ACO programs without triggering difficult state regulatory requirements originally designed for traditional health insurance companies.

The General Assembly passed House Bill 287 – Amend Insurance Laws, which clarifies that Medicare ACOs are not subject to state insurance regulation since they are already overseen by the Centers for Medicare and Medicaid Services (CMS). The provision is limited to ACOs and the delivery of medical services to Medicare patients through the Medicare Shared Savings Program, the Next Generation ACO Model, and other current and future Medicare ACO programs.

This statutory change not only resolves considerable uncertainty, but also removes a regulatory barrier to our local pursuits of the triple aim and value-based health care. It comes at a welcome time, too, as more physicians consider forming or joining ACOs in anticipation of Medicare payment reforms under MACRA.

2016 APPROPRIATIONS ACT

CSRS UPGRADES AND PRESCRIBER REGISTRATION

HB 1030 / S.L. 2016-94

NCMS has long supported the state’s Controlled Substance Monitoring System (CSRS) as a tool to inform physician prescribing of controlled substances. This year the General Assembly tucked some important, positive changes to the CSRS into its annual budget bill.

An oft-cited shortcoming with the CSRS is its lack of integration with other registries, databases and health information technology. This year, the General Assembly squarely confronted this problem. In an attempt “to improve the security, functionality and interface capabilities” of the CSRS, the 2016 budget allocated \$600,000 to upgrade the CSRS so it may connect to other state prescription drug monitoring systems and the NC Health Information Exchange. A separate appropriation of over \$1 million also was made to improve analytics of the prescription drug data reported to the CSRS.

The General Assembly also was motivated to address the low rates of CSRS registration and usage by prescribers. As in years past, multiple proposals were made to require prescribers to not only register with the CSRS, but also to check a patient’s prescription drug history prior to writing a prescription for a controlled substance. One such proposal even threatened prescribers with misdemeanor or felony charges for not consulting the CSRS. (NCMS opposed this particular proposal and worked to prevent its passage.)

What did eventually pass in 2016 is a requirement that physicians and all other prescribers register to use the CSRS. While a mandate to check the CSRS also was close to passage, it was dropped late in the session at the request of NCMS, NC College of Emergency Physicians, the NC Society of Anesthesiology, NC Pediatric Society and others. To enforce the new registration mandate, the North Carolina Medical Board will require each physician and PA to attest to CSRS registration upon the renewal of the individual’s license. This attestation must occur within 30 days of the renewal. The Board may suspend or revoke a license if a licensee fails to register with the CSRS and/or fails to make the attestation.



STATEWIDE STANDING ORDER FOR NALOXONE

SB 734/ S.L. 2016-17

As part of the response to the opioid epidemic plaguing communities across the state, and with support from the North Carolina Medical Society, the legislature swiftly passed Senate Bill 734.

This bill specifically authorizes the State Health Director to issue a statewide standing order for the dispensing of the drug, Naloxone, which can reverse the effects of opioid-related overdose. Under the standing order, pharmacists may dispense Naloxone directly to individuals who meet any of the enumerated criteria. No prescription from a physician is required for either the intranasal or intramuscular/injectable applications.

When Governor Pat McCrory signed SB 734 into law on June 20, State Health Director Randall Williams, MD, simultaneously issued the standing order. North Carolina became the third state in the country to implement a statewide standing order in an attempt to make the drug more accessible to those at risk of opioid overdose.



For more information about Naloxone and North Carolina's standing order, please visit www.naloxonesaves.org,

BRINGING MANAGED CARE REGULATIONS INTO MEDICAID (A.K.A. "THE CHAPTER 58 AMENDMENT") DRAFT AMENDMENT NOT ADOPTED IN 2016

Over the years, the state has passed many laws to curb abusive business practices by commercial managed care companies. These laws – sprinkled throughout Chapter 58 of the General Statutes – require prompt payment of claims, accurate provider directories, uniform credentialing processes, fair contracting, freedom from most-favored nation clauses, and more. These "rules of the road" have become bedrock principles in how managed care companies interact with physicians in our state; however, as currently written, these laws will have questionable applicability to the prepaid health plans (PHPs) that are eventually selected to operate the Medicaid program.

We want to fix that. NCMS supports clear, consistent application of and compliance with these rules by health insurers that operate in any or all North Carolina markets. In pursuit of that result, we worked with other state specialty societies and provider groups to push an amendment (known as "the Chapter 58 amendment") late in the 2016 Short Session.

While key leaders in both the House and the Senate shared our vision, the Session adjourned before our proposed amendment could be added to a bill and passed into law. With at least a couple more years before Medicaid PHPs go-live in North Carolina, there will be additional opportunities to have this issue resolved.

PROVIDER-LED ENTITIES IN MEDICAID REFORM

S.B. 838 / S.L. 2016-121

One unique characteristic of last year's Medicaid reform legislation is the invitation for "provider-led entities" or "PLEs" to compete directly with traditional managed care companies to serve Medicaid patients on a statewide basis. The legislation also gives PLEs an exclusive opportunity to operate Medicaid plans on a regional basis. Under the reform legislation, an entity may qualify as a PLE if (1) a majority of the entity's ownership is held by an individual/organization whose primary business purpose is to operate as a Medicaid provider, and (2) the majority of the entity's governing body is composed of physicians, PAs, NPs or psychologists.

To ensure that the PLE model is viable and attractive, NCMS supported some changes to the definition of PLE outlined above. First, the majority ownership component was expanded beyond individuals or entities that operate as Medicaid providers to also include entities whose purpose is to operate a Medicaid health plan under reform. Second, the governance component was amended to specify that the individual providers on the governing body had to hold licenses to practice in North Carolina and have experience treating Medicaid patients.

These changes were incorporated into S.B. 838, sponsored by Sen. Ralph Hise, which was passed and signed into law on July 28, 2016.



STEP THERAPY PROTOCOLS & ABUSE-DETERRENT OPIOIDS

HB 1048

This session Rep. David Lewis (R, Harnett) introduced House Bill 1048, which proposed two changes to how commercial health insurers administer prescription drug benefits in North Carolina.

First, the bill would require insurers that choose to place newer "abuse-deterrent" prescription opioid medications on prior authorization to impose identical prior authorization requirements on each opioid not considered "abuse-deterrent." The bill also would prohibit health plans from first requiring patients to use an opioid without an abuse-deterrent formulation before an abuse-deterrent version of the drug could be used.

Second, the bill sought to reform how insurers design and implement step therapy protocols by requiring the protocols to be evidence-based, developed by experts unaffiliated with the insurer, and consistently updated to reflect new evidence. Step therapy protocols also would be subject to an exceptions process accessible by the patient and the prescriber when certain criteria are met.

After considerable discussion and debate, this bill did not make it out of the House Insurance Committee. It will likely be introduced again in 2017.

MEDICAL PRACTICE ACT CHANGES FOR THE BETTER

HB 728/S.L. 2016-117

Three years of work by a coalition of physician-driven organizations ended successfully with the passage of H728, making important changes to the NC Medical Practice Act (MPA).

Foremost among them is an increase in the Board's annual registration fee. The additional revenue addresses a chronic negative cash flow problem at the NCMB. In prior years, the Board had taken steps to improve efficiency and conserve funds. But operating costs have increased, driven by changes in physician practice and adaptation of the regulatory structure to ensure the Board is fulfilling its charge.

NCMS has long-supported the self-regulation of medicine. The recent US Supreme Court decision in *NC State Board of Dental Examiners v. FTC* underscores the attention required to ensure the learned professions remain self-regulated. Chronic underfunding of the Board's work would invite shifting this authority to a state bureaucracy.

Other major MPA changes in H728 include:

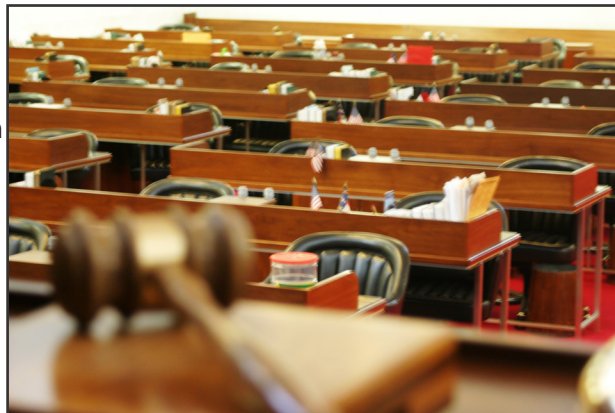
1. Clarification that the NCMB cannot deny or revoke a license solely because the individual fails to obtain board certification. (This is in response to physician concerns over Maintenance of Certification, as implemented by many ABMS member boards.)
2. Elimination of a longstanding and vexatious requirement that hospitals report suspensions of privileges for failure to timely complete medical records.
3. Clarification of the statute authorizing the North Carolina Physician Health Program to ensure physicians have access to any assessment of them by the program or a treatment provider. Safeguards against any such assessment becoming admissible in a civil action also are part of H728.
4. More specific term limits for Medical Board service. In the future, a physician that has served more than 72 months on the Board will not be eligible for another term.
5. Clarification that the documents and records reviewed by the Medical Board Review Panel (which vets candidates for NCMB service) are not public records.
6. A mandate that the Medical Board Review Panel timely disclose lists of a) physician candidates to be interviewed and b) nominations to the Governor.
7. Authority for the Medical Board Review Panel to interview, discuss and vote on physician candidates in closed session.
8. A requirement that once charges are issued against a licensee, discovery will occur in compliance with the NC Rules of Civil Procedure. In addition, the bill clarifies that a licensee may, upon request, receive certain information the Board obtains during its investigation.

The hard work and perseverance of our coalition partners made these improvements a reality. The coalition faced significant challenges, but remained together and focused on the goal. Coalition partners are NCMS, NC Medical Board, NC Physician Health Program, and Cumberland County Medical Society. Significant support was also provided by an engaged and knowledgeable team of North Carolina-based medical organizations who are active at the NC General Assembly.



TORT REFORM REVISITED - PATTERN JURY INSTRUCTIONS

In 2011, the NC General Assembly passed a comprehensive set of medical malpractice reforms in Senate Bill 33, which sought, in part, to increase the standard for proving negligence in any medical malpractice case emanating from the “furnishing or failure to furnish professional services in the treatment of any emergency medical condition” from the greater weight of the evidence to that of clear and convincing evidence. This standard increase was meant to be applicable to all duties and actions associated with emergency medical claims.



Now five years later, the North Carolina Pattern Jury Instruction Committee has proposed jury instruction changes that have interpreted the law passed in Senate Bill 33 to limit the new standard of proof to only the duty of compliance with the standards of practice set forth under the General Statutes, but not the common law duties to use best medical judgement for reasonable care and diligence. This is a problem since both breaches of duty are commonly asserted in a medical malpractice case.

NCMS has been working to amend the statute by adding the phrase “or a violation of any common law duty” in order to clarify the original intent of the legislation. This phrase would then include the common law duties of a doctor’s best medical judgement under the clear and convincing standard of proof. NCMS was not able to get this legislation through during the 2016 session, but will continue to advocate for it in the next session.

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PO Box 27167, Raleigh, NC 27587 | Phn: (919) 833-3836 | Web: www.ncmedsoc.org