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Monthly Report

April 2009

From the President

Joseph P. Costabile, MD

The recent amendment and passage of the Codey Bill allowing physicians the ability to utilize their own ambulatory surgical centers (ASC) or centers in which they have invested gave me a moment to reflect. The amendment is a result of physicians through our lobbyists and spokespersons "fighting city hall" to the benefit of our profession and our patients' care. It seemed months ago the bill would pass with restrictions on our ability to use our own centers and work places because the government said so. Too many times, in the past, we have thrown our hands up in frustration and defeat before a bill has even been presented. I have heard physicians say "well if they, the legislators already have it in a bill, it's a done deal. There is no use fighting it." Without our reviewing and questioning the validity and in some cases fighting these bills and regulations, the professy is fulfilled. A good example of this is the state regulation regarding cardiac surgeons to perform 100 cardiac surgical cases at each institution where they practice. They felt it couldn't be successfully fought. Now they have to live with it.

As both the state and federal government become more intrusive on the practice of medicine, creating mandated guidelines and benchmarks that clearly miss the point or create misinterpreted results, we must remain vigilant and challenge these rules, regulations and bills before they become laws and are forced upon us. If we do not look out for ourselves and our patients best interests no one else will. Misinformed, albeit well meaning, law makers despite their best intentions are not only incorrect, but pose a threat to doctors and the patients for whom we care. Congratulations to our hard working advocates for their efforts. Let us continue this effort into the future.

April 1, 2009

The Legislature has recessed for its traditional budget break, and will reconvene in May. The only activity during the month of April will be conducted by the Senate and Assembly Budget Committees who will hear from all the Commissioners as they present their Department's budgets.

During the month of March, I continued work on the patient safety legislation. You may recall, from past newsletters, that we testified on the Senate version, S-2471, in the Senate Health Committee. During that testimony, we voiced numerous concerns, particularly with the provision that prohibits payment to physicians who admit they caused one of the designated hospital-acquired conditions.

The Senate version was released from committee, and was poised for a full Senate vote. At the last minute, it was remanded back to the Senate Health Committee and, on March 10, and further amended to:

1. add discoverability protection; and
2. establish a collaboration between the Commissioners of Health and Senior Services and Banking and Insurance and the Director of the Division of Consumer Affairs in the Department of Law and Public Safety to develop standards for health care providers and third party payers to implement the billing prohibition provisions.

Following adoption of these additional amendments, S-2471 passed the full Senate on March 16, 38 to 0.

On March 9, the Assembly Health Committee had a "for discussion only" hearing on the measure on its version, A-3633. I have excerpted my testimony below which I delivered on the bill:

Thank you for the opportunity to speak on A-3633.

First, we're confused as to why the physicians were only recently included in the discussions -- that apparently took place over the course of a year - as this measure was drafted.

This is a major piece of legislation - with new standards not found in any other state in the nation - and far reaching negative implications for the medical community and the patients they serve.

We urge you to move slowly and deliberately as the bill progresses -- to make sure the intent of the legislators is in fact what the bill says.

We are very familiar with the Centers for Medicare and Medicaid Services and the work at the federal level to limit or eliminate payment to hospitals and physicians for so-called "never events" and hospital acquired conditions.

Our colleagues at the national level have been at the table with CMS working on these provisions.

There are currently three "never events" for which physicians are not paid for their Medicaid and Medicare patients. These include surgery on the wrong patient, wrong body part or wrong site.

We have no argument at all that these "never events" should rightly penalize the physician.

This bill seeks to expand this penalty - in the form of non-payment - to 8 other "hospital acquired conditions" currently found on the CMS list. Things like "falls and trauma" and "catheter-associated infections."

The problem we have with this penalty is that it's very difficult to attribute these "conditions" to the attending physician.

Physician payment for conditions outside the three "never events" is an area that is being explored by CMS and others, but it is not ready for prime time.

Physicians regularly attend "morbidity and mortality" conferences, usually weekly, where each physician discusses complications on his or her patients, most of which are inevitable. In effect he "admits" on many patients having had a part in the evolution of events that include the complication. Currently, the proceedings of M&M conferences are legally protected information. We are gravely concerned over how this bill will impact frank discussions of complications and adverse events after surgical procedures - which is a common and necessary part of good quality improvement in all hospitals.

Physician attribution is very difficult to assess in a hospital setting where so many staff have hands on responsibilities with the patient.

When this bill was heard in the Senate, the Senate Health Committee approved amendments that establish that physician will not be penalized unless he or she admits that the fault was theirs.

Does this bill impact physicians who are 100% responsible for the adverse event? What if he or she is only 10% at fault - and the hospital or staff is 90% at fault?

What about the ancillary physician support? If an orthopaedic surgeon admits to being 100% at fault for a fall following surgery, is the anesthesiologist or radiologist reimbursement affected?

This bill would not only prohibit payment to the attending physician who "caused" the hospital-acquired condition, it would also expand the non-payment to the private sector payers - not just Medicaid and Medicare.

This is also precedent setting legislation found no where else in the country.

We can't give the private carriers -- who are already eager to find any reason to delay or halt physician payment - any new excuse to do so.

I know you agree that we need not penalize those who treat the most vulnerable, with the least access to preventive care.

And of course, we all know that the trial lawyers will be chomping to get their hands on any reporting so they can swoop in with med mal lawsuits. We understand there are amendments being prepared that provide safeguards on the discoverability of the reporting....this is critical so it doesn't further exacerbate New Jersey's tenuous medical liability environment.

We respectfully request that you continue to work with us on this important legislation to ensure that the "patient safety" legislation truly improves the care of patients. In its current form, we disagree.

Chairman Herbert Conaway, MD, and the members of his committee listened intently to the various testimony, and appeared, through their verbal responses and questions, to agree with many of the concerns we addressed. No official action on the bill was conducted. We will continue to work on this issue as the session continues. Stay tuned.

Legal Report

Mark E. Manigan, Esq.

Update Regarding Garcia Decision

On Monday, March 23, 2009, Governor Jon S. Corzine signed into law S-787, Senate President Richard J. Codey 's bill amending the 1991 Codey Law.

The amendments modify the Codey Law by (1) creating a clear-cut exception from New Jersey's ban on self-referrals for referrals to ambulatory surgery centers ("ASCs"); (2) deeming all pre-effective date referrals to ASCs compliant with the Codey Law; and (3) permitting corporate ownership of licensed ASCs to continue.

Enactment of these amendments arrives 14 months after the infamous Garcia decision in which the judge ruled, notwithstanding previous guidance from the NJ Board of Medical Examiners to the contrary, that a physician's self-referral to an ASC violated the 1991 Codey Law. The concern after the Garcia decision was that many insurance carriers, relying on Garcia, would seek to deny or recoup ASC reimbursement as the carrier in Garcia was seeking to do. In fact, a few other carriers had begun, most prominently Liberty Mutual, to allege Codey Law violations not only as an excuse for denying payment, but also as grounds for an insurance fraud claim. The Codey Law amendments were enacted despite fierce efforts by the auto insurance industry to derail them.

Soon after the publication of the Garcia decision, WolfBlock filed emergency applications with the NJ Board of Medical Examiners to issue further advisory guidance on the Codey Law. In response, the Board adopted an emergency rule which would have created an exception for ASC referrals. While Attorney General Anne Milgram declined to consent to the enactment, the Board's emergency action, combined with Attorney General Milgram's stated interest in ensuring that ASCs continued to get paid for services rendered, combined further with Senator Codey's introduction of legislation in January 2008, helped "stop the clock." For the most part, in our view, this dissuaded insurance carriers from taking undue advantage on the Garcia decision and preserved the status quo.

The amendments to the Codey Law increase regulatory oversight of the entire ASC industry by requiring, within one year of March 23, 2009, that (1) all unlicensed one-room ASCs to become "registered" with NJDOH and (2) all licensed ASCs to become accredited by an "accrediting body recognized by Medicare" (currently The Joint Commission, the Accreditation Association for Ambulatory Healthcare and the American Association for the Accreditation of Ambulatory Surgery Facilities, hereafter collectively referred to as an "Accrediting Body").

The conditions of unlicensed one-room ASC "registration" include the requirement that these centers obtain (1) Medicare certification or (2) accreditation from an Accrediting Body. Further, only existing unlicensed ASCs, as well as those that have construction plans filed by the 6 month anniversary of the effective date of the bill will qualify for "registration" and therefore the ASC self-referral exemption contained in the amendments. The amendments also permit registered centers to (1) transfer ownership; and (2) relocate (a) within 20 miles or (b) to a "Health Enterprise Zone" (provided there was no expansion in the relocated ASC's scope of services). Finally, the amendments do not subject "registered" ASCs to the ambulatory care facility assessment (currently 2.95% on gross receipts and capped at \$200,000 per year).

With regard to the future development of licensed ASCs, the amendments prohibit the New Jersey Department of Health from issuing new ambulatory surgery facility licenses unless one of the following scenarios apply: (1) ASCs in development -- meaning entities that have filed architectural plans within 6 months of March 23, 2009; (2) the transfer of ownership in a grandfathered ASC; (3) the relocation of a grandfathered ASC provided the relocation is (a) within 20 miles, or (b) to a "Health Enterprise Zone," and (c) that there is no expansion in the relocated ASC's scope of services; (4) new ASCs that are owned in whole or in part by a New Jersey hospital; or (5) new ASCs that are owned in whole by a medical school.

Finally, the amendments abolish exceptions for lithotripsy and radiation oncology by prohibiting physicians from referring patients to lithotripsy or radiation oncology entities in which they hold an interest, unless the interest "was held" within one year following the effective date of the bill.

Court Holds That Agreement Between Hospital and Anesthesia Group Violates Federal Stark Law

In a decision issued on January 21, 2009, *United States v. Carlisle HMA, Inc.*, 554 F.3d 88 (3d Cir. 2009), the United States Court of Appeals for the Third Circuit held that a hospital and anesthesia group's arrangement for the anesthesia group to provide pain management services did not meet the personal services exception of the federal Stark Law. New Jersey is within the area of jurisdiction of the Third Circuit.

In 1992, the hospital at issue in the case (the "Hospital") contracted with an anesthesia group (the "Group") to provide anesthesiology services at the Hospital on an exclusive basis. No pain management services were provided by the Group at that time, but the agreement contained certain provisions that suggested that they could be provided in the future. Under the agreement, the Group was to provide anesthesiology coverage on a 24 hour/7 day a week basis and the Hospital would provide space, equipment and supplies for the provision of anesthesia services or pain management services at no cost to the Group. The agreement also provided that if the Hospital should open another facility, the Group would be provided with the opportunity to provide anesthesia and pain management services at that facility.

In 1994, the Group began providing pain management services at the Hospital. In 1998, the Hospital built a new stand-alone facility which contained a pain clinic located approximately three miles from the Hospital. From the day that it opened, the Group provided pain management services to the patients at the pain clinic on an exclusive basis. The Hospital provided space, equipment and support personnel at the pain clinic free of charge to the Group. The parties did not amend the 1992 agreement or enter into a new agreement for the provision of these services. As the parties did under the 1992 agreement, the Hospital billed for the facility fees for the services and the Group billed for the professional component of its services.

The suit was brought by a former member of the Group who alleged that the provision of the pain management services at the pain clinic violated the federal Stark Law's and the federal anti-kickback law's prohibition of submitting claims to Medicare for services rendered by a physician having a referring relationship with an entity. The district court below found that the 1992 agreement extended to the Group's provision of pain management services at the pain clinic, but the Court of Appeals disagreed and reversed that decision.

The Court of Appeals determined that the 1992 agreement did not extend to the provision of "services at a non-existent facility." Therefore, it determined that the personal services exception to the Stark Law could not apply to the pain management arrangement because the exception requires that the arrangement be set out in writing. The Court of Appeals further noted that the provision of pain management services is of greater concern under the Stark and anti-kickback

laws, because while hospitals influence the flow of business to physicians for traditional hospital-based practices such as anesthesiology, "in pain management, a physician in an outpatient clinic is in a position to generate substantial business for a hospital."

The Court of Appeals was also concerned that the Hospital and the Group did not establish that the consideration provided for the Group's provision of pain management services reflected the fair market value for such services. Indeed, the Court of Appeals determined that "a negotiated agreement between interested parties does not 'by definition' reflect fair market value." The Court of Appeals further observed that when one party is in a position to refer to the other party, negotiated agreements are often designed to disguise the payment of non-fair-market value compensation and that further evidence is required to demonstrate that the remuneration provided is that of fair market value.

Therefore, the Court of Appeals reversed the decision of the district court and remanded the case for further proceedings consistent with its opinion. This decision is an important reminder that parties should enter into new agreements when the services provided under an original agreement are either expanded or altered, in scope or location, to ensure that the arrangements continue to meet the applicable exceptions to the Stark and anti-kickback laws.

Union County Judge Orders Hospital to Resume Support for Patient in Vegetative State

A recent case decided by Judge John F. Malone, P.J.Ch., in Union County may have significant impact upon hospitals and other health care providers seeking to remove life-sustaining treatment in futile cases. The Judge ultimately granted an injunction against the hospital and appointed the daughter, who was arguing for continued treatment, as guardian empowered to make health care decisions on her father's behalf. Significantly, the Judge refused to adopt the hospital's argument that continued treatment was medically futile.

By way of background, the patient in this case was admitted to Trinitas Regional Medical Center in Elizabeth, New Jersey ("Trinitas") for surgery for a malignant thymoma. Following the surgery, the patient experienced complications, which resulted in oxygen deprivation and lapse into unconsciousness. The patient became ventilator-dependent and received nutrition via a feeding tube. The patient was subsequently admitted to various treatment facilities and then re-admitted to Trinitas with a diagnosis of renal failure. At that point, the patient also began receiving dialysis treatments.

Hospital representatives advised the patient's family that the patient was in an unresponsive irreversible vegetative state and that further treatment would be futile. The medical providers were of the opinion that the life-sustaining treatment should be withdrawn.

The patient's daughter then initiated a court action, seeking a temporary restraining order enjoining the hospital from discontinuing life-sustaining treatment pending further court proceedings. During the proceedings, various family members testified that they disputed the assessment that the patient was in an unresponsive, persistent vegetative state. They believed the patient could respond to certain stimuli. The family also testified that they believed the patient to be "a strong willed person who would not give up... and would want to continue to receive treatment."

The physicians testifying in the matter stated that the patient was in a persistent vegetative state from which he will never recover, that he was actively dying, and suffering from ulcers on his bones due to chronic infection and bed sores. The physicians further testified that continuation of treatment was medically futile and contrary to the standard of care.

Judge Malone stated in his written opinion that the question before the court was "whether a medical provider on its own initiative can terminate life support services for a patient. The defendant argues that the issue is better framed as whether a medical provider may be required to provide medical care to a patient where the treatment is futile, against the standard of care and inhumane. However stated, counsel for both parties suggests (sic) that the issue has not been addressed by the courts of this state."

The judge then discussed various seminal New Jersey cases, including *In re Quinlan*, 70 N.J. 10 (1976) and *In re Conroy*, 98 N.J. 321 (1985). The plaintiffs argued that these cases hold that the decision to withhold treatment is that of the patient or surrogate decision maker. The hospital argued that these cases are inapplicable to the matter before Judge Malone. That is, the hospital argued that the issue was not whether treatment should be withdrawn, but whether physicians should be forced to provide futile medical care which they believed to be inhumane, against the standard of care and medically and ethically inappropriate.

Judge Malone concluded that "resolution of the issue presented in this case must be guided by the principles enunciated by the Supreme Court in *Matter of Jobes*, 108 N.J. 394 (1987)." Judge Malone summarized that case as establishing the principle that "it is not the role of the trial court to decide whether treatment should be removed from a comatose patient but rather to establish criteria that respect the right to self determination and protect incapacitated patients." The "substituted judgment" doctrine is thus triggered, which allows a surrogate decision maker to consider the patient's personal value system to determine if life support systems should be removed.

Judge Malone thus opined: "The decision to continue or terminate life support systems is not left in the courts. The position of the hospital argues that the court take the role of the surrogate decision maker. The hospital seeks to have the court exercise its judgment in determining the proper course of treatment for [the patient], a task which the Court in *Jobes* rules is outside the role of the court." Judge Malone appointed the patient's daughter as the guardian of her father, and to act as her father's surrogate decision maker, including the right to make medical treatment decisions.

The written decision of Judge Malone, although not a "published" opinion, may nonetheless impact judges in future New Jersey cases on similar issues. Unfortunately, Judge Malone did not instruct the healthcare providers as to how to square his decision with the professional and ethical dilemma of medical futility.

OIG Advisory Opinion 09-01.

The Department of Health and Human Services Office of Inspector General ("OIG") recently issued Advisory Opinion 09-01, which provides guidance on a proposed program concerning provision of complimentary local transportation to friends and family of residents of a skilled nursing facility. The OIG found that the program (i) would not constitute grounds for the imposition of civil monetary penalties ("CMP") under 42 U.S.C. 1320a-7a (the Civil Monetary Penalty ("CMP") law), and (ii) although the proposal could implicate the Anti-Kickback Statute if the requisite intent to induce or reward federal referrals were present, the OIG would not impose administrative sanctions.

By way of background, the party requesting the opinion is a not-for-profit skilled nursing facility ("Facility") that is not easily accessible by public transportation and which, for some resident families, requires crossing a \$9.00 toll bridge. The Facility proposes to provide complimentary local transportation to friends and family of its residents using a company-owned, employee-

driven van. Pick-ups and drop-offs will be at certain designated public locations, and transportation will be offered only to the Facility's premises. The Facility noted that such transportation will be offered uniformly to all its residents, regardless of the resident's income level, a resident's source of payment, or the level of care provided to the resident. According to the Facility, the value of the transportation may exceed \$50 annually, but none of the costs related to the transportation will be claimed on any Federal healthcare program cost report or claim.

In its analysis, the OIG first set forth several "general observations" related to free transportation programs offered by Federal healthcare program providers to potential referral sources. The OIG noted that, although some free transportation programs are important and beneficial to patient care, such arrangements also could be used fraudulently for inappropriate patient steering, overutilization, and the provision of medically unnecessary services. Given the potential for abuse, the OIG stated that such arrangements must be evaluated on a case-by-case basis. The OIG identified a non-exhaustive list of factors to consider in such evaluation, including:

- Transportation offered in a manner related to referrals;
- Luxury or specialized transportation;
- Geographic area for transportation;
- Availability of other means of transportation;
- Marketing or advertising;
- Transportation destination; and
- Treatment of the costs of the free transportation.

The OIG then analyzed the arrangement in light of the foregoing factors and concluded that, although the arrangement differs from usual programs that offer free transportation services to passengers who are patients obtaining treatment, the Anti-Kickback Statute and CMP law were nonetheless potentially implicated. This was because the value of the transportation per household may exceed \$50 annually. Notwithstanding this, the OIG concluded that the proposed complimentary transportation program poses a low risk of fraud and abuse. As a result, the OIG declined to impose administrative sanctions under the CMP law and the Anti-Kickback Statute.

In reaching its conclusion, the OIG noted that: the transportation will not be provided to residents to obtain Federally-payable items or services or to benefit referral sources; the transportation will not be offered selectively to certain Federal program beneficiaries; the type of transportation will be reasonable and will not include limousines or other expensive transports; the transportation will only be offered and advertised locally; the availability of local public transportation is limited; the program is consistent with the Facility's mission; and there will not be shifting of costs to any Federal healthcare program.

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