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Healthcare Update

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Physician Recruitment Issues

By Daniel J. Mohan

On March 26, 2004, the Centers for Medicare and Medicaid Services ("CMS") issued Phase II of its proposed Final Rules to the Stark II statute. The effective date of these Final Rules was July 26, 2004. In these final rules, CMS issued rules clarifying the requirements of many of the statutory Stark II exceptions, and also created several new administrative exceptions. Among the modifications to the existing statutory exceptions, the most significant modification proposed by CMS were changes to the physician recruitment exception. The following is a brief outline of the requirements under the new regulations with respect to the physician recruitment exception. In a general sense, the new rules provide greater clarity with respect to permissible recruitment arrangements. Be advised, however, that the new rules effect fundamental changes to recruitment arrangements that involve the recruitment of a physician to an existing practice.

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Generally, the physician recruitment exception protects "remuneration" that is provided to a physician in order to induce that physician to relocate his or her medical practice to the geographic service area served by the hospital. Note, first, that the new rule speaks in terms of the relocation of the physician's ***medical practice***. Thus, the exception is met if the physician relocates his or her medical practice to the geographic area served by the hospital; the physician is not required under the terms of the exception to relocate his or her residence, as well.

Under the rule, the physician must relocate his or her medical practice to the "geographic service area served by the hospital;" and, this term is specifically defined in the rule. The term "geographic service area served by the hospital" is defined as "the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its patients." Therefore, in order to meet the terms of the exception, the recruited physician must establish his or her medical practice in the hospital's geographic service area, as defined in the rule. As a result, any type of recruitment arrangement which has as its purpose the recruitment of a physician to an area outside of the geographic service area of the hospital would ***not*** meet the terms of the exception, and therefore would violate Stark II (unless the arrangement can be structured in a way to meet a different Stark II exception).

In addition, the term "relocate" is specifically defined under the rule. Under this definition, a physician must either move his or her medical practice at least 25 miles from the physician's existing medical practice, or the physician must derive at least 75 percent of his or her medical practice revenue in the new practice from professional services furnished to patients that the physician did not see or treat at his or her prior medical practice site during the preceding three years (i.e., at least 75 percent of the revenue in the new practice must come from new patients). For the first or "start-up" year of the practice, this 75 percent test would be satisfied if there is a "reasonable expectation" that the physician's practice will meet this test. Thereafter, the physician must document that he or she has met this 75 percent test. Note that CMS has also specifically permitted assistance agreements between a hospital and a resident or a physician who has been in practice for less than one year,

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Department of Community Health Adopts New Certificate of Need Regulations

By Robert C. Threlkeld

The certificate of need program in Georgia has been the source of substantial debate and controversy over the past year. For example, a recently filed lawsuit has challenged the constitutionality of the certificate of need program, contending that it violates the prohibitions on anti-competitive laws embodied in the Georgia Constitution. The contours of the statute and the administration of it continue to be litigated by a number of providers at the agency level, and in Georgia's lower and appellate courts. Meanwhile, the Department of Community Health (the "Department"), the agency in Georgia responsible for administration of the certificate of need ("CON") statute, has been active in enforcing the statute and in adopting new regulations to implement the statute.

Overview of Proposed New Regulations

The Department adopted a number of proposed new regulations governing the CON program in Georgia effective as of January 5, 2005. The new

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Physicians Look To Patients To Help Defray Rising Malpractice Insurance Premiums

By Kimberly B. Greaves

Ever increasing medical malpractice premiums continue to plague healthcare providers around the country. As of June 1, 2004, the AMA categorized nineteen states as facing a medical liability insurance crisis; Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Mississippi, Missouri, Nevada, New Jersey, New York, North Carolina, Ohio, Oregon, Pennsylvania, Texas, Washington, West Virginia and Wyoming. Twenty-five other states are considered to be showing signs of trouble.

In addition to lobbying for tort perform, providers are debating and testing other possible solutions to help them pay increased premiums. A very controversial tactic being employed by some physicians is to impose upon patients a "liability surcharge" to help defray the increases in insurance premiums. This is also seen as a way to pull the support of patients into the tort reform lobby by making it the patient's problem too.

Rising overhead costs and static reimbursement have already led a growing number of physicians, particularly those in less lucrative primary care specialties such as pediatrics, family practice and internal medicine, to begin imposing administrative or access charges for routine services that they once provided for free (for example, taking after hours calls, responding to email questions, filling out disability camp and work absenteeism forms and assisting patients with insurance questions). Some physicians have also begun charging fees for missed appointments or late cancellations.

Taking what seems to be one of the more extreme measures with regard to surcharges to defray soaring liability insurance cost, a Connecticut OB/GYN practice announced that it will began charging an extra $500 per pregnancy. The group's announcement touched off a litany of positive and negative responses from the medical community and government officials. The Connecticut Attorney General immediately questioned the charge, issuing a "consumer warning" urging any pregnant woman assessed the fee to contact his office because "it is most likely illegal."

Other less aggressive tactics have been employed by physicians who asked their patients for a "donation." A Florida physician sent his three thousand patients a letter asking for a $125 check ($25 for those under twenty-five) to help pay his $30,000 insurance bill, which has quadrupled since 2002. His letter was so successful, he plans on sending another one before next year's premium is due. While postured as a voluntary donation, some physicians criticize these letters as being coercive to patients who might feel that if they do not contribute, they will not be treated as well by the doctor.

Imposing a liability surcharge, some argue, is just another access fee. But others argue that it is at least unfair if not unethical, or even illegal. The issue has touched off a debate in many states and prompted the AMA to pass a resolution at its June 2004 meeting to study the issue and make recommendations. AMA

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Medical Staff Issues: An Awakening Giant

By Sidney Summers Welch

The tensions between hospitals and physicians have, in recent years, subsided somewhat as these formerly often adversarial factions have been united in efforts against managed care. This progress has been beneficial as it has united hospitals and physicians in common goals -- namely, the ultimate goal of collaboration and partnership in working to ensure the provision of safe, high quality care to patients in the hospital. These common objectives were previously ignored by hospitals and Medical Staffs, which instead allowed adversarial actions, documentation, or hyperbole distributed by lawyers or at seminars, to place them at odds. Many times, the source of the tension derived from seemingly benign Medical Staff Bylaws or policies and procedures drafted without the input of the hospital or the physicians that, in practice, did not serve the mutual objectives of ensuring the delivery of quality care in a fair way.

On occasion, the unnecessary animosities created by one-sided documents are the result of anti-physician or anti-hospital legal counsel, or legal counsel that is uneducated in one or both sides of Medical Staff/hospital issues. For this reason, separate counsels, with expertise in Medical Staff Bylaws, and a balanced perspective should be selected by hospitals and Medical Staffs to assist in these matters. Other times, the tension is created by a difficult personality – either from the hospital side or the physician side - taking an inflexible position. The *San Buenaventura* case below is a perfect of example of both of these problems.

However, in an environment where economic competition among hospitals is increasing, physicians are investing in alternative income sources that often compete with the hospitals, and hospital budgets are tightening. Hospitals, Medical Staffs, and physicians alike need resist the return to previous tensions. The emerging trend, as discussed in several of the cases below, is a return to practices known as "economic credentialing," which has been defined as "the use of economic criteria unrelated to quality of care or professional competence in determining a physician's qualification for initial or continuing hospital medical staff membership or privileges." American Medical Association, Policy H-230.975: Economic Credentialing. *See also* American College of Medical Quality, Policy 19: Economic Credentialing. To prevent this relapse, all parties need to be educated and to pay careful attention to the meanings and implications of certain Medical Staff and hospital bylaws provisions and their respective policies and procedures (and the absence of the same) to make sure that these documents retain some semblance of a constructive environment for patient care. Otherwise, all parties will become entangled in unnecessary and costly battles of wills to try to resolve difficult situations. Some tension between the hospital and the Medical Staff is an inevitable part of the systems

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State Managed Care Plan Leaves More Questions Than Answers

By Deepak J. Jeyaram

In an effort to control sky rocketing costs and severe budget problems, the Georgia Department of Community Health ("DCH") has proposed drastically reforming the state's current Medicaid system by adopting a mandatory managed care format for specific categories of Medicaid recipients. DCH estimates that if the current system remains unchanged, as of FY 2005, the Medicaid budget will require 43 percent of Georgia government's new revenue. That number will grow to 50 percent by FY 2008. Though details about the new system are sketchy, here is what is known.

The DCH managed care strategy involves segmenting the state into six (6) regions and contracting with care management organizations ("CMOs") to provide and manage all services provided to the Medicaid recipients enrolled in each region. Five of the regions will have two CMOs per region while the sixth region, which includes Atlanta, will have three to five CMOs. Specific cost savings will be achieved through effective utilization management of Medicaid recipients' health needs and through lower administrative costs rather than through cutting reimbursement to enrolled providers. In addition, DCH envisions that holding the CMOs contractually accountable for recipient access to quality health care will lower overall utilization of services.

DCH's last foray into managed care was the less than successful Georgia Better Healthcare ("GBHC") system. One of the problems with GBHC was that enrollment in the program was optional. Under the new CMO system, Medicaid recipients will be required to enroll in a CMO in their region. Initially, mandatory CMO enrollment will only extend to Low Income and Right From The Start categories of Medicaid eligibility. It is unclear whether DCH plans on rolling out its managed care initiative to other categories of eligibility in the future. It is important to note that CMOs will not have responsibility for long term services like Intermediate Care Facilities for the Mentally Retarded, nursing home and hospice services, and Home and Community based waiver services programs

Another problem that plagued DCH during the GBHC era was the inability to determine when a recipient was actually enrolled in GBHC as under that system, a recipient was free to switch coverage every thirty (30) days. This made it difficult for providers to determine whether they were providing services to an appropriate individual which, at times, resulted in denial of payment for the provider's services. Under the proposed CMO system, a recipient will select a CMO in his or her region and will have ninety (90) days to change to a different CMO without cause. Once the ninety (90) day period has passed, the recipient will be "locked in" to his or her chosen CMO for a period of one (1) year, thus, hopefully eliminating enrollment uncertainty for providers.

The CMO procurement will be a competitive process and, as such, details concerning the Request For Proposal ("RFP") have been closely guarded by DCH. What is known is that each CMO will have to be licensed by the Georgia Department of Insurance as a risk bearing entity and will, therefore, be subject to the State's net worth and solvency standards as well as statutory requirements for timely payment of a "clean claim." Additionally, DCH has emphasized the importance of the CMOs having sufficient infrastructure to support all of the State's modernization initiatives. For example, the CMOs should have in place the basis for telemedicine and electronic prescribing. Another requirement will likely be substantial member education initiatives in addition to the standard disease and case management functions. Finally, in light of DCH's revitalization of its Program Integrity section, CMO's will likely be required to submit monthly fraud and abuse reports to the Department.

There is also some certainty as to what the appeal processes will look like as there are several federal regulations and state statutes that require DCH to offer, at a minimum, specific avenues of appeal. An initial proposition, federal regulations mandate that CMO's be required to offer an internal grievance process, after which the aggrieved provider will likely have the option to request an administrative review of the issue directly from DCH, as is the current practice. If the provider still wishes to appeal, it has a right to an administrative hearing conducted by the Office of State Administrative Hearings. Finally the administrative hearing decision can be appealed to Superior Court. Though the addition of a grievance process to the existing DCH appeals process seems like an additional administrative hoop for the provider to jump through, resolving disputes prior to the administrative hearing is in the best interest of the provider and the grievance system provides an additional avenue for resolution.

As Georgia's healthcare community waits for DCH to release the RFP (see schedule below) there are several important questions left unanswered. Foremost among these questions is how the CMOs will make a profit while still lowering costs for the state. Despite reassurances from DCH, providers fear that reimbursement rates may be cut. Also unclear is what the CMOs will use a basis for reimbursement. For hospital groups, will CMO's be free to choose between DRG and per diem reimbursement methodologies or will DCH mandate a uniform statewide practice? Whatever the answer, it is incumbent on the healthcare community and its advocates to make sure that the RFP has sufficient detail to address these types of concerns. ❑

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DCH MANAGED CARE SCHEDULE:

1. **1/05 - RFP released**
2. **2/1/05 – RFP bidders conference**
3. **3/21/05 – Bids due**
4. **5/1/05 – Winners of RFP announced**
5. **5/20/05 – Contracts with winning CMOs finalized**
6. **11/1/05 – Atlanta and one (1) other region go active**
7. **1/07 – Other four (4) regions go active.**

Recent On-Call EMTALA Developments

By Brynne R. Goncher

In 1986 Congress passed the Emergency Medical Treatment and Labor Act ("EMTALA"), which requires hospitals with emergency departments to provide a medical screening examination to any individual who comes to the emergency department and requests such an examination, and prohibits hospitals with emergency departments from refusing to examine or treat individuals with an emergency medical condition ("EMC").[1] On September 9, 2003 the Centers for Medicare and Medicaid Services ("CMS") issued final regulations to clarify a hospital's obligations under EMTALA ("New Regulations"). The New Regulations became effective November 10, 2003. On May 13, 2004, CMS issued interpretive guidelines, Appendix V – Interpretive Guidelines – Responsibilities of Medicare Participating Hospitals in Emergency Cases ("Interpretive Guidelines"), which revised guidelines previously issued by CMS. The Interpretive Guidelines became effective immediately upon their publication. The Interpretive Guidelines break down the New Regulations and provide detailed interpretation. The Interpretive Guidelines serve as an instruction manual for CMS surveyors and therefore provide significant guidance for hospitals and physicians. The New Regulations and the Interpretive Guidelines together provide for significant changes and clarifications in a variety of areas. One of the most significant changes was the addition of a section pertaining to the availability of on-call physicians.[2] Specifically, the changes and clarifications affect hospital requirements for back-up call panels, whether hospitals can refer emergency department patients to on-call physicians' offices, how on-call physicians can use telemedicine, whether physicians who elect not to take call may choose to take call for certain patients, the consequences of an on-call physician's failure to respond, and the response time required in on-call policies.

Hospital on-call requirements stem from current statutory law. Under 42 U.S.C. 1395cc, hospitals are required to adopt and enforce a policy to ensure compliance with EMTALA and maintain a list of physicians who are on-call for duty after the initial examination to provide treatment necessary to stabilize an individual with an EMC.[3] The New Regulations require hospitals to maintain a list of physicians who are on-call for duty after the initial examination.[4] The New Regulations added to this previous requirement, stating that each hospital must maintain an on-call list of physicians on its medical staff in a manner that best meets the needs of the hospital's patients who are receiving services in accordance with the resources available to the hospital, including the availability of on-call physicians.[5]

One of CMS' purported purposes in addressing on-call lists in the New Regulations was to clarify the extent of the on-call list requirements. CMS added language in the New Regulations that "Each hospital must maintain an on-call list of physicians on its medical staff in a manner that best meets the needs of the hospital's patients who are receiving services in accordance with the resources available to the hospital, including the availability of on-call physicians." While this language alone arguably does not truly clarify a hospital's on-call coverage requirements, the Interpretive Guidelines do somewhat clarify the requirements. The Interpretive Guidelines state that "The hospital must have policies and procedures (including back-up call schedules or the implementation of an appropriate EMTALA transfer) to be followed when a particular specialty is not available or the on-call physician cannot respond because of situations beyond his or her control."[6] The Interpretive Guidelines further explain that if a hospital elects to allow on-call physicians to schedule elective surgery during the time the physician is on-call or has simultaneous on-call duties, the hospital should have planned back-up in the event the physician is unable to respond due to elective surgery or other on-call duties.[7] In addition, the Interpretive Guidelines require hospitals who have physicians taking calls simultaneously at more than one hospital to have policies and procedures to follow when the on-call physician is not available, including, but not limited to, procedures for back-up on-call physicians or the implementation of an appropriate EMTALA transfer.[8] (Also of important note is that hospitals that allow physicians to be on-call at more than one hospital at a time must be aware of the physician's on-call schedule.[9] As illustrated above, the Interpretive Guidelines point to many situations when hospitals should have back-up call panels. Therefore hospitals may be required to have back-up call panels in order to comply with EMTALA.

Second, the Interpretive Guidelines also address the ability of on-call physicians to see emergency department patients in their offices. In the past, hospitals have questioned whether a hospital may send a patient who presents in the emergency department to an on-call physician's office instead of the on-call physician coming to the emergency room. The Interpretive Guidelines state that this is generally unacceptable. However, if it is medically appropriate to do so, the treating emergency physician may send an individual in need of emergency treatment to the on-call physician's office if the office is part of a hospital-owned facility (department of the hospital sharing the same Medicare provider number as the hospital) and on the hospital campus.[10] In determining whether a hospital has appropriately moved a patient from the hospital to the on-call physician's office, surveyors will consider (1) whether all persons with the same medical condition are moved in such circumstances, regardless of their ability to pay for treatment; (2) whether there is a bona fide medical reason to move the patient; and (3) whether appropriate medical personnel accompany the patient. Since its application is so limited, hospitals should exercise caution in sending patients in need of emergency treatment to an on-call physician's office.

Third, the Interpretive Guidelines also address the use of telemedicine by on-call physicians. They state that physicians may utilize telemedicine for individuals in need of further evaluation and/or treatment to stabilize an emergency medical condition only when, because of the individual's geographic location it is impossible for the on-call physician to physically assess the patient.[11] Permissible situations include an individual who presents to a hospital in a rural health professional shortage area ("HPSA") or in a county outside of a metropolitan statistical area ("MSA").[12] Therefore hospitals and physicians should be careful in utilizing telemedicine to evaluate and treat individuals with an emergency medical condition.

Fourth, the Interpretive Guidelines address the ability of physicians to take selective call. Some physicians may request to take call only selectively for patients with whom they or a colleague may have an established patient-physician relationship. The Interpretive Guidelines state that a physician who chooses to selectively take call for certain patients while at the same time refusing to see other patients (including those individuals whose ability to pay is questionable) may violate EMTALA.[13] More definitively, a hospital that permits physicians to selectively take call while the hospital's coverage for that service is not adequate, the hospital would be in violation of EMTALA by encouraging disparate treatment.[14] Therefore hospitals should use extreme caution before allowing physicians to take selective on-call, and physicians should use extreme caution in deciding to provide on-call services selectively.

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Fifth, the Interpretive Guidelines also give hospitals and physicians important guidance on an on-call physician's failure to respond to call. Specifically, the Interpretive Guidelines state that if an on-call physician does not fulfill his or her obligation to respond to a call, but the hospital arranges for another staff physician in that specialty to assess the individual, and no other EMTALA requirements are violated, the hospital may not be in violation of EMTALA.[15] A physician who fails to come to the hospital may be in violation of the law, however, even if hospital is able to arrange for another physician to respond.[16]

Sixth, the Interpretive Guidelines also address response time. It is generally understood that physicians must respond to calls within a reasonable period of time. The Interpretive Guidelines provide that hospitals are responsible for ensuring that on-call physicians respond within a reasonable period of time. Interpretive Guidelines, Tag A404. The Interpretive Guidelines clarify that the response time must be stated in minutes in the hospital policies and should not use ambiguous terms such as reasonable or prompt.[17] These terms are not sufficient under EMTALA because they are not enforceable by the hospital.[18]

Other notable comments from the Interpretive Guidelines include the fact that individual physician names, not physician group names, are required to be included on the on-call list.[19] CMS does not have specific requirements regarding the frequency in which on-call physicians are expected to be available to provide on-call coverage.[20] The Interpretive Guidelines also make clear that there is no predetermined ratio CMS uses to identify how many days hospitals must provide medical staff on-call coverage based on the number of physicians on staff for a particular specialty.[21]

Together with the New Regulations, the Interpretive Guidelines provide helpful guidance on back-up requirements, referrals to on-call physicians' offices, the on-call use of telemedicine, selective call, failure to respond to a call, and response time language. They offer valuable assistance in complying with EMTALA, and hospitals should consult them in drafting and amending their on-call policies. ❑

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(Endnotes)

[1] 42 U.S.C. 1395dd et seq.
[2] C.F.R. 489.24(j).
[3] 42 U.S.C. 1395cc(I)(i) and (iii).
[4] 42 C.F.R. 489.20(r)(2).
[5] 42 C.F.R. 489.24(j).
[6] Interpretive Guidelines, Tag A404.
[7] Id.
[8] Id.
[9] Id.
[10] Id.
[11] Id.
[12] Id.
[13] Id.
[14] Id.
[15] Interpretive Guidelines, Tag A404.
[16] Id.
[17] Id.
[18] Id.
[19] Interpretive Guidelines, Tag A404.
[20] Id.
[21] Id.

Medical Staff Issues: An Awakening Giant

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of checks and balances that exist between those that own the facility (and have the concomitant financial responsibilities associated therewith) and those who actually provide patient care. However, that tension should exist in an educated environment of mutual respect, rather than hostilities created by one-sided Medical Staff or hospital bylaws.

The following is intended to provide a summary of recent cases addressing Medical Staff issues and to provide guidelines to Medical Staffs and their legal counsel in drafting, amending, and adopting provisions of the Medical Staff Bylaws that reflect a cohesive and constructive effort between the hospital and members of the Medical Staff.

Medical Staff of Community Memorial Hospital of San Buenaventura v. Community Memorial Hospital of San Buenaventura.[1] This significant litigation was pending in the Superior Court of California, Ventura County when it was settled in September of 2004, following resignation of the hospital's chief executive officer, who was replaced by a more physician-friendly administrator. The Medical Staff of San Buenaventura Community Memorial Hospital filed suit against the hospital, its trustees, and a medical management company operating the hospital. The allegations in the litigation included (1) unilateral amendment of the Medical Staff Bylaws by the hospital; (2) hospital interference in internal Medical Staff processes, such as voting rights and medical staff meetings; (3) unauthorized imposition of a code of conduct and conflict of interest policy by the hospital on the Medical Staff; (4) hospital appointment of physicians to Medical Staff processes; and (5) conversion of Medical Staff treasury by the hospital. By way of example, the hospital adopted policies where any physician who has a financial stake in an entity that competes with the hospital could not hold a Medical Staff leadership position or vote as a staff member. The hospital also adopted a "Medical Staff Code of Conduct," giving itself the authority to investigate and discipline physicians who do not meet its standards. The hospital unilaterally amended the Medical Staff Bylaws to conform to the hospital bylaws.

In August of 2003, the court held that the Medical Staff – the entity bringing the lawsuit – is a legal entity, capable of suing the hospital and its trustees. The court did emphasize that, although the Medical Staff is entitled to sue on behalf of the Medical Staff membership as a whole, it has no right to sue on behalf of the interests of its individual physician Medical Staff members.

City of Cookeville v. Humphrey.[2] On February 24, 2004, the Tennessee Supreme Court rendered a decision reversing the previous rule that publicly owned hospitals in Tennessee had to allow staff privileges to all professionally qualified physicians. In reaching its decision, the court concluded that a recent statutory amendment had changed this law, thereby allowing hospitals to consider economic factors in credentialing physicians. The statute calls for hospital board bylaws to take precedence where there is a conflict between medical staff and hospital board bylaws. This decision has a potentially dramatic impact as the Alfredson[3] case is widely cited as the authority preventing economic credentialing in Medical Staff/clinical privileges decisions.

Lo v. Provena Covenant Med. Ctr.,[4] In this case, Dr. Lo filed suit seeking a temporary restraining order preventing the hospital, without Medical Staff input, from unilaterally summarily suspending his clinical privileges to perform open heart surgery

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without requiring that physician to "relocate" his or her practice, provided that the physician establishes his or her practice within the hospital's geographic service area. This provision addressed an apparent anomaly in the statutory exception which seemed to prohibit a hospital from providing assistance to a resident, even though that resident had no established patient base, because the resident would not be "relocating" his or her practice to the geographic service area served by the hospital.

As we mentioned above, the most significant changes to the physician recruitment exception were made with respect to arrangements involving income assistance arrangements provided to a physician in connection with the recruitment of that physician to an existing practice within the geographic service area served by the hospital. A "recruitment to an existing practice" arrangement that involves an income assistance component must meet all of the following criteria in order to meet the exception:

1. *The hospital, the recruited physician and the existing practice must all sign the assistance agreement.*
2. *The hospital may reimburse the practice directly for "actual costs incurred" by the practice in recruiting the new physician (for example, the hospital may reimburse the practice for a recruitment fee paid by the practice in recruiting the physician). Other "remuneration," however, such as reimbursement for relocation expenses or a "signing bonus," must pass directly through to or remain with the recruited physician.*
3. *In connection with the income assistance arrangement, costs allocated by the practice to the income assistance arrangement cannot exceed the "actual additional incremental costs attributable to the recruited physician."*
4. *The physician group must retain the records which specify the actual additional incremental costs incurred by the group in connection with the recruitment and employment of the new physician for five years.*
5. *The group cannot impose "additional practice restrictions" on the recruited physician, such as a non-compete covenant or similar restrictive covenants.*
6. *The remuneration paid by the hospital under the arrangement may not be determined in a manner that takes into account the volume or value of any actual or anticipated referrals by the recruited physician or the physician practice.*
7. *The arrangement may not violate the federal Anti-Kickback Statute or any federal or state law or regulation governing billing or claims submission.*

Any hospital or physician contemplating a potential physician assistance agreement must ensure, as a threshold matter, that the physician can meet one of the two alternative "relocation" tests to ensure that the physician will be deemed to have "relocated" his or her practice, as this term is contemplated under the rules; and, the parties must ensure that the physician will establish his or her medical practice within the "geographic service area" of the hospital, as that term is defined in the rules.

In addition, to the extent that the proposed assistance arrangement includes an income guarantee or assistance deal, this arrangement may no longer be structured as either a traditional "gross income" or a "net income" deal, to the extent that the "net income" deal includes allocation of general overhead and business expenses of the practice, and to the extent that the "gross income" deal includes a "factor" for overhead expenses. Instead, the arrangement must be structured as one in which the hospital essentially ensures that the practice will collect enough money on services rendered by the recruited physician to cover the "actual additional incremental costs attributable" to the recruited physician (including the physician's salary). To the extent that the group does not collect sufficient revenue to cover these direct additional incremental expenses, the hospital may reimburse the group for the shortfall.

The new rule does not "grandfather" existing assistance arrangements. Therefore, any existing arrangement which does not meet all of the criteria of the exception, as established under the new rules, must be immediately amended in order to bring the arrangement into compliance with the exception. ❑

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officials have said that they plan to release a report at the AMA's December interim meeting in Atlanta.

Surcharges of any type are definitely not permitted by Medicare or Medicaid, which do not allow physicians to charge extra for services already covered by a government insurance program. Several private third party payors have already said that they will not pay these surcharges, and some have warned that their payor contracts with providers prohibit any sort of mandatory charges beyond deductibles or co-pays to be imposed on the patients.

Practices considering such measures should do so with caution before adding access fees of any kind, even voluntary ones, that some patients might feel to be intimidating. The idea may backfire with patients as they become angered by the charges and leave the practice. Others may even pursue action against the physician or practice due to the perceived coerciveness of the charge. Additionally, managed care and insurance plan contracts should be reviewed carefully for terms prohibiting such charges. Therefore, physicians should proceed with caution as this is a very gray area right now for which all the legal and ethical ramifications have not yet been fully considered and determined. ❑

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in the absence of a supervising physician. Dr. Lo claimed that, by such unilateral action, the hospital had breached the Medical Staff Bylaws. The trial court granted the TRO, but the Illinois Appellate Court reversed its decision, finding that the hospital had not breached the Medical Staff Bylaws because the hospital administration, and not the medical staff, under the JCAHO standards, has "the [ultimate] authority to render … renewal or modification of clinical privileges decisions." The Illinois Supreme Court declined to hear an appeal of the case, and the trial court dismissed Dr. Lo's case. This decision is important because of the potential precedent that the hospital's decision making trumps that of the Medical Staff due to the "ultimate authority" and responsibility that the hospital bears. However, this case may be distinguished from others in that the Medical Staff failed to take any action in this case – in other words, in the absence of action by the Medical Staff, the hospital was forced to act – and authority exists in support of the proposition that the Medical Staff also bears the responsibility, and therefore the authority, for making clinical, as opposed to administrative, decisions.

Lawnwood Medical Center v. Lawnwood Medical Center Medical Staff.[5] Two physicians, individually and on behalf of the Lawnwood Medical Center's Medical Staff, filed suit in Florida Superior Court seeking a declaration that a Florida statute[6] providing that, in the event of conflict between hospital bylaws and Medical Staff Bylaws, the hospital's bylaws prevail with respect to medical staff privileges, quality assurance, peer review, and contracts for hospital-based services, is unconstitutional under Florida and federal law. Historically, the hospital repeatedly tried to remove Medical Staff officers elected under the Medical Staff Bylaws and suspend Medical Staff members under processes that were different from those provided under the Medical Staff Bylaws. The Medical Staff prevailed in those instances. This litigation has resulted from the hospital's proposed changes to the Medical Staff Bylaws that confirm that the hospital would control those areas delineated by the statute (Medical Staff privileges, quality assurance, peer review, and contracts for hospital-based services.) The litigation is still pending.

Eastern Maine Medical Center. In this litigation, which parallels a recent trend in economic credentialing cases, cardiologists on the Medical Staff began performing certain procedures they had previously performed in the hospital in their offices. One of those cardiologists represented the Medical Staff as an *ex officio* member of the hospital's Board of Trustees and was removed. The Medical Staff elected one of his partners to the hospital Board. These debates have temporarily been resolved with the election of four candidates, sympathetic to the Medical Staff, to replace hospital Board members.

Baptist Health v. Murphy[7] Keeping with the theme of economic credentialing, this case considers whether a hospital's economic credentialing violates federal and state antikickback laws. The hospital adopted a "Conflict of Interest Policy," which requires all professional Medical Staff members to disclose any direct or indirect ownership or investment interests in competing hospitals to the hospital. Any such physician is ineligible for initial or renewed appointment. Because the plaintiff physicians violated the policy, the hospital notified them that their Medical Staff membership and clinical privileges would be terminated. The plaintiffs claimed that the hospital's purported economic rationales were nothing more than pretext for a policy that rewards Medical Staff membership and privileges to physicians who refer most of their patients to the hospital. The court granted the plaintiffs' injunction, allowing them to remain on the Medical Staff as long as they could meet the criteria outside the conflict policy, expressing its believe that it is likely that plaintiffs will prevail at trial. The hospital appealed, and the Arkansas Supreme Court has assumed jurisdiction.

Biddulph/Mountain View Hospital v. HCA/Eastern Idaho Regional Medical Center.[8] Like the *Murphy* case, this case also involves a Conflict of Interest policy and economic credentialing. The hospital adopted a Medical Staff Development Plan, which was specifically rejected by the Medical Staff. The plan states that physicians who apply or reapply for Medical Staff privileges must disclose any financial interests in competing facilities, and, if the hospital Board determines that the physician has a significant economic conflict, it may impose conditions on the physician's staff privileges, such as (1) requirements that the physician not consider economic incentives when making patient referrals and, (2) if the Board determines, "by objective criteria," that a practitioner is diverting patients to other facilities for reasons related to that practitioner's financial or other gain, it may, in its discretion, remove that practitioner's appointment and clinical privileges. Not surprisingly, the Medical Staff Bylaws do not establish economic criteria as requirements for Medical Staff appointments or clinical privileges or as grounds for adverse action. The hospital unilaterally terminated the privileges of five members of the Medical Staff because they were investors in another competitor hospital. The hospital alleged that the physicians "abuse[d] their 'insider' status at the hospital -- access to patients and to sensitive proprietary information – to their own advantage and to the hospital's detriment," and "steer[ed] a lop-sided share of well-insured profitable cases from the hospital to facilities the physicians owned." The hospital subsequently rescinded the termination but the policy has remained in effect. The physicians sued. At last check, this litigation was still pending.

Gluscic v. Avera St. Luke's Hospital.[9] On July 31, 2002, the South Dakota Supreme Court concluded that Avera St. Luke's Hospital was entitled to terminate a physician's Medical Staff membership and privileges for reasons not set forth in the Medical Staff Bylaws. However, those reasons were very fact and case-specific. In this litigation, Dr. Gluscic had been admitted to the Medical Staff during a time period where physicians had sued the hospital challenging the validity of economic criteria for Medical Staff membership. The lower court had granted an injunction, prohibiting the hospital from denying applications from physicians due to economic criteria. When that lower court's decision granting injunctive relief was overturned, Dr. Gluscic's appointment to the Medical Staff was terminated. The South Dakota Supreme Court affirmed this decision to terminate Dr. Gluscic's Medical Staff membership even though the Medical Staff Bylaws did not cite this ground as one for termination. This case may have limited application in light of its very specific facts. However, arguably, the general principle allowing for termination for unstated but implied grounds could be argued in the future.

O'Byrne v. Santa Monica-UCLA Medical Center.[10] On December 20, 2001, the California Court of Appeal held that Medical Staff Bylaws do not establish a contract between the Medical

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Staff and the hospital. This decision contradicts generally accepted California law on this issue. *See e.g. Janda v. Madera Community Hosp*., 16 F.Supp. 1181 (E.D. Cal. 1998); *Scott v. Lee*, 208 Cal. App. 2d (1962). Dr. O'Byrne did not appeal this decision to the California Supreme Court and the California Medical Association requested the California Supreme Court depublish the decision. This request was denied. Accordingly, it remains to be seen whether this decision will be adopted by other California courts.

Exeter Hosp. Med. Staff v. Bd. of Trs. Exeter Health Res., Inc.[11] On November 14, 2002 and August 28, 2003, the New Hampshire Supreme Court and trial court, respectively, reached decisions on two important Medical Staff issues. In this case, Dr. Windt, President of the Medical Staff at Exeter Hospital, and the Medical Staff of Exeter Hospital brought suit against the hospital and its parent corporation when it sought to prohibit Dr. Windt from disclosing the details of his disagreement with the hospital over the information he received as a Medical Staff ex officio representative on the hospital Board of Trustees. The court dismissed the Medical Staff from the suit, claiming it did not have the legal capacity to sue the hospital. The Medical Staff appealed. The Supreme Court, although finding in Dr. Windt's favor (i.e. he was entitled to communicate information concerning his disagreement with the hospital to other members of the Medical Staff), concluded that hospital Medical Staffs are subordinate administrative units, dependent upon and accountable to the hospital and its trustees and, therefore, are incapable of suing the hospital or its trustees.

Manvar, Buddhadev Md v. Board of Trustees of Brooklyn Hospital Center.[12] In early 2003, the Medical Staff of Brooklyn Hospital Center won a lawsuit it filed challenging the hospital's decision to replace elected Medical Staff officers with people selected by the hospital. The judge ordered reinstatement of the Medical Staff officers but did not rule on whether the hospital's bylaws supersede Medical Staff Bylaws when there is a conflict. Prior to the issuance of the court order, the Board of Trustees amended the corporate bylaws and Medical Staff Bylaws, eliminating the authority of the Medical Staff officers to carry out the responsibilities of the Medical Staff. The Judge felt this issue should be resolved in a separate suit, which was filed in June of 2003. Not long thereafter, a new CEO was appointed and the parties agreed to a continuance to try to resolve these issues.

Trend to "Conflict of Interest" Policies. Hospitals across the nation have been adopting "Conflict of Interest" policies preventing members of their Medical Staffs from holding any type of interest in a competing facility. Those supporting such policies attribute their necessity to a preservation of the capital and resources invested in the facility. However, others challenge such policies on grounds that they are anticompetitive, such as the policy adopted by Ohio Health, in response to doctors' investment in another for-profit surgical hospital, and in the *Murphy v. Baptist Health* and *Biddulph* cases, and concerns that they act to the detriment of patient care by limiting physicians' choices.

New JCAHO Standards. Currently, the JCAHO Standards, specifically MS.2.4.1, states that "The medical staff bylaws, rules and regulations, and policies and the governing body's bylaws do not conflict." The JCAHO Standards have not contained a provision prohibiting unilateral amendment of the Medical Staff Bylaws. The resulting problem was that hospitals (including, but not limited to, *San Buenaventura*) were arguing that they had to unilaterally amend the Medical Staff Bylaws in order not to be in violation of the JCAHO standard prohibiting conflicts between corporate and Medical Staff Bylaws. By passing MS.1.30 EP2, which states "Neither the Medical Staff Bylaws nor the governing body bylaws have language that provides for unilateral amendment of the Medical Staff Bylaws or rules and regulations," prohibiting unilateral amendment, hospitals and Medical Staffs will be forced to collaborate to find mutually acceptable solutions to problem rather than the rancor, resentment, blame, demonization and polarization that results from unilateral amendment and detracts from a functionally healthy hospital. However, because this standard addresses amendment only, both the hospital and the Medical Staff still need to make sure that what they adopt as Medical Staff Bylaws, hospital bylaws, rules and regulations, and policies and procedures, truly reflect their collaborative goals of quality patient care.

Additionally, M.S. 1.20, EP 19, which has recently been added, provides that, when administrative procedures for corrective actions, fair hearing and appeals, credentialing, privileging and appointment are in supplemental documents, the approval process must be described in the bylaws; criteria to identify what can be in the supplemental documents must be in the bylaws; and administrative procedures must be approved by the Medical Staff and Governing Body through the bylaws-described mechanism. In jurisdictions where Medical Staff Bylaws create contract or a quasi-contractual enforceable obligation, hospitals and Medical Staffs must pay careful attention as to which obligations, policies, and procedures are placed in the bylaws and which are placed in supplementary, non-binding documents. Due to the significant potential impact of this proposal, JCAHO has solicited comments on this proposal, and further guidance is required from JCAHO on this standard and Element of Performance.

Stay tuned . . . ❑

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(Endnotes)

1 Civ. 219107 (Cal. Superior Court, Ventura County).

2 *126 S.W.3d 897 (Tenn. 2004) (affirming* 2002 Tenn. App. LEXIS 817)

3 *Lewisburg Community Hosp., Inc. v. Alfredson, 805 S.W.2d 756 (Tenn. 1991)*

4 *796 N.E.2d 607 (Ill. App. Ct. 2003)* Hitting close to home, Radiation Therapy Oncology v. Providence Hospital is currently pending, where the court will decide if the hospital can circumvent the by-laws to close the radiology department. (Ala. S. Ct.)

5 Pending, St. Lucie County and Leon County, Fla. Cir. Cts.

6 St. Lucie County Hospital Governance Law Act, 2003 Fla. HB 1447

7 *2004 Ark. LEXIS 436 (Ark. July 1, 2004).*

8 Pending, Bonneville County, Idaho, Dist. Ct.

9 649 N.W.2d 916 (S.D. 2002).

10 114 Cal. Rptr. 2d 575 (Cal. App. 2d Dist. 2001).

11 810 A.2d 53 (N.H. 2002).

12 Docket No. 0007489/2003, New York State Supreme Cts., Kings County.

regulations effect substantial changes governing the purchase of diagnostic and other equipment in Georgia by health care providers and facilities that are subject to the CON statute. They also memorialize existing Department practice with respect to whether the costs for a project are "associated with and simultaneously developed and proposed" so that aggregation of those costs is required in determining whether a CON must be obtained. Finally, although the Department had issued proposed new regulations respecting physician owned, single specialty ambulatory surgery centers, the determination of what is indigent care for purposes of the statute, and the level of indigent care a healthcare provider must offer, after substantial public comment respecting those regulations, the Department determined not to adopt those proposed regulations.

Background To CON Statute

The CON law, codified generally at O.C.G.A. § 31-6-1, governs when a healthcare provider or health care facility must obtain a CON respecting the provision of a particular healthcare service, the expenditure of funds on health care equipment or on capital items generally. First adopted in Georgia in 1982 following the repeal of the short lived federal CON law, the CON statute generally provides that before a "new institutional health service" may be offered in Georgia, the person or entity proposing to offer the service must first obtain a CON. Generally, for any person or entity seeking to offer a health care service or make an expenditure on health care equipment, the first question to ask is whether they will be offering a new institutional health service. If so, then before actually offering the service that person must first obtain a CON. Failure to receive that approval can have significant adverse consequences. The CON statue empowers the Department to levy fines of up to $5000.00 per day for failure to comply with the statute. The Department also asserts that it has the authority to shut down any new institutional health care service that fails to comply with the statute. Indeed, over the past year the Department has moved boldly to require compliance with the CON statute by a variety of healthcare providers who had skirted or ignored its requirements.

The Department also asserts that it has the authority to shut down any new institutional healthcare service that fails to comply with the statute. Indeed, over the past year the Department has moved boldly to require compliance with the CON statute by a variety of healthcare providers who had skirted or ignored its requirements.

Under the CON statute, a new institutional health service can include, among other things: (a) the construction or development of a "new health care facility" such as a hospital, a diagnostic, treatment or rehabilitation center, an ambulatory surgical or obstetrical facility, a home health agency or a personal care home; (b) capital expenditures by or on behalf of a healthcare facility in excess of a set capital expenditure threshold – which currently stands at $ 1,322,451.00; (c) the purchase or lease by a healthcare facility of certain diagnostic or therapeutic equipment with a value in excess of a defined threshold, which is currently set at $ 734,695.00; (d) the purchase, lease or use by a diagnostic, treatment or rehabilitation center of diagnostic or therapeutic equipment with a value in excess of a set threshold, which currently stands at $ 734,695.00; (e) the offering of new clinical health services by a healthcare facility that had not previously offered on a regular basis within the prior twelve month period, and (f) any increase in the bed capacity of a healthcare facility, with certain defined exceptions.

The CON statute also makes clear that certain health care providers are not required to seek a CON. In this connection, the CON statute makes explicit that physicians and dentists need not obtain a CON in connection with their practice of medicine. The CON statute also provides that physicians of a single specialty who propose to operate an ambulatory surgical center do not need to obtain prior CON review, provided that in developing the ambulatory surgical center they do not exceed the established expenditure threshold for those centers, which currently is $1,436,356.00.

The CON statute and its regulations also provide a mechanism for a healthcare provider to seek guidance from the Department as to whether a CON is required for a particular healthcare project. The Department will consider and, if appropriate, issue determination letters indicating whether a proposed project in the health care area is subject to prior CON review. The Department will also issue what is known as a Letter of Non Reviewability ("LNR") with respect to the acquisition of certain diagnostic or therapeutic equipment, the making of certain capital expenditures, as well as the development of physician owned, single specialty ambulatory surgical centers. In those instances, the Department may issue an LNR indicating that the proposed expenditure does not exceed the applicable cost threshold to trigger CON review. Strictly speaking, a provider need not obtain an LNR for an equipment purchase or a capital expenditure, if it is certain that the expenditure does not exceed the applicable threshold. The Office of Regulatory Services, which among other things licenses ambulatory surgical facilities, however, requires either an LNR to be issued or a CON to be granted before licensing a physician owned, single specialty ambulatory surgical facility.

New Equipment Regulations

The new regulations that the Department has adopted, among other things, are intended in particular to memorialize Department policy in connection with the purchase of diagnostic or therapeutic equipment. It is in the area of diagnostic or therapeutic equipment that much controversy has sparked respecting the enforcement of the CON statute. Part of that controversy grew out of the proliferation of new imaging centers – whether hospital based or otherwise - that were avoiding CON review. The new regulations provide significant clarity and guidance in this area.

Under the new regulations, the Department has now made clear that all diagnostic and therapeutic equipment that a provider proposes to purchase will be considered under the specific cost counting requirements of the Department's regulations; previously, on their face the cost counting requirements had applied only to magnetic resonance imaging machines. Among the costs that the Department requires be disclosed include the base price of the unit; any expense incurred for the purchase of a first year warranty; expenses for installation, assembly and operator training; expenses incurred for any extra packages associated

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with the equipment, such as special software packages; the dollar amount of any volume or bulk purchase discounts; transportation and insurance costs; and any dollar amount attributable to a first year service contract. Moreover, the regulations now require that any request for a LNR must include a separate build out/finish line item valuation sheet, listing all dollar amounts attributable to build out to make the equipment functional. Department Rule 111-2-.1-.01(44)(d)(1). Significantly, any expenditure that is associated with and simultaneously developed with the purchase of the equipment, such as construction of space to house the equipment or construction of waiting rooms and office space must be included. Department Rule 111-2-1-.01(44)(d)(6).

In addition to specifying the costs of the specific equipment, the new regulations require the disclosure of any additional piece of equipment that is simultaneously acquired and associated with any particular piece of diagnostic equipment. Under this new regulation, the Department may aggregate the costs of diagnostic equipment that is simultaneously acquired and associated with other equipment, *regardless of the particular imaging or other diagnostic modality in question*. Department Rule 111-2-.1-.01(44)(d)(2)&(3).

One net effect of this regulation is to preclude a provider from parsing out individual pieces of equipment that would be associated with one another, and then contending that because any individual piece of equipment might pass under the threshold, all pieces purchased together should avoid CON review. Interestingly, and perhaps controversially, the regulations take the position that associated pieces of equipment, and any associated build out, will be considered under the equipment expenditure threshold, rather than the somewhat higher capital expenditure threshold. As for what is simultaneous, the Department considers any equipment purchased within six months to be purchased simultaneously. Department Rule 111-2-.1-.01(44)(d)(3).

The question of whether a project — that potentially could be subject to CON review — is simultaneously developed and associated with another project or expenditure for purposes of counting costs under the threshold may be determinative of whether a CON is required.

It is unclear, however, how expansively the Department will interpret its new regulation. For example, under a strict interpretation of the new regulation, if a provider were to purchase a computerized tomography scan machine for use in an imaging center, and separately purchase an ultrasound machine for use in a perinatal service, the costs of the two pieces of equipment could be aggregated for purposes of the equipment threshold. As indicated below, however, the Department also has separately promulgated a new regulation that will afford it discretion in such matters.

The new regulations also impose follow up cost reporting requirements, similar to those that the Department imposes upon physician groups that obtain an LNR. Thus, upon acquisition of the equipment, a person obtaining the LNR must obtain a final statement of the total costs. In addition, if the equipment is not obtained within 180 days of the issuance of the LNR, then an interim cost statement must be submitted within two weeks of the expiration of the 180 day period, and subsequent cost statements must be submitted each ninety day period thereafter.

Additionally, the new regulations expand upon the affidavit requirements in connection with seeking a LNR for equipment purchases. A party must swear not only that the costs as disclosed are correct, but that for a period of six months after the acquisition the party will not acquire additional items that are to be added or used with the particular equipment, nor acquire additional equipment that is reasonably related to or associated with the general type of service that the proposed equipment would provide.

Replacement Equipment

The new regulations also define what is "replacement equipment." This is an important concept, because if equipment is "replacement equipment," then regardless of whether the expenditure threshold has been met, a CON is not required. The regulations now require that for equipment to qualify as replacement equipment, the old equipment must have undergone and received prior CON approval. Further, the old equipment must be removed from the premises, and the replacement equipment must be placed in the same location as the old equipment was housed. Further, the replacement equipment must be comparable. What this means is that it is "functionally similar" and "used for the same diagnostic or treatment purposes." Department Rule 111-2-2-.03 (16). However, and crucially, replacement equipment is not comparable if (a) the prior equipment was used and the replacement equipment is less than three years old, or (b) the replacement equipment is new, the existing equipment was reconditioned and acquired less than three years previously, or (c) the replacement equipment is capable of performing procedures that could result in the provision of a new procedure that the old equipment could not provide.

Expenditures That Are "Associated With And Simultaneously Developed Or Proposed"

The new regulations provide important clarity to the Department's position on whether a particular project or expenditure is "associated with and simultaneously developed or proposed" with another project or expenditure for purposes of the equipment purchase threshold, the capital expenditure threshold, or the threshold for single specialty ambulatory surgical centers. O.C.G.A. § 31-6-2(14). The Department's administration of its existing regulations and the CON statute has been the source of substantial litigation. The new regulations are an attempt to memorialize and emphasize what the Department contends has been its existing policy regarding this concept. This is an important area of concern for healthcare providers. That is because the question of whether a project—that potentially could be subject to CON review—is simultaneously developed and associated with another project or expenditure for purposes of counting costs under the threshold may be determinative of whether a CON is required.

Under the new regulation, "associated with our simultaneously developed or proposed" means that if the Department *in its discretion* determines that a single project "or the substantial equivalent" of a single project "is divided into separate components which are associated with an which are developed or planned simultaneously, so that the project or the substantial

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equivalent of a project or any component thereof does not require a total capital expenditure in excess of the capital expenditure or diagnostic or therapeutic equipment threshold, the Department shall combine the components" for purposes of determining whether the threshold has been exceeded." Further, the regulation provides that the "Department shall include items and expenditures which are related and which occur simultaneously in computing an applicable threshold" regardless of whether the individual items or expenditures are below the threshold and regardless of whether the items may otherwise be non-reviewable. Department Rule 111-2-1-.01(8).

The relevant analysis for determining whether an expenditure is associated with or simultaneously developed or proposed, therefore, is twofold. On the one hand, the Department has reserved to itself the discretion in determining whether the triggering requirement that the project is a single project or the substantial equivalent of a single project to require aggregation of costs. If that determination is yes, then the addition of all costs is mandatory.

In assessing whether an item is associated with and simultaneously developed or proposed, the Department focuses not only on the relatedness of the items, but also on the timing of the acquisitions. In this connection, the Department has promulgated a new regulation that the Department strongly considers to reinforce its existing policy on timing. The regulation indicates that the Department "shall determine that expenditures *related* to activities, services and items are simultaneously developed or planned if such expenditures occur within a six month period." Department Rule 111-2-2-.01 (8)(b). The six-month period shall run from operation of the activity or service in question to the date of "initial capital expenditure on the second activity or item or from operation of the activity or item to operation of the second activity or item." Id. This is an important re-emphasis of an existing policy that has been the fount of substantial litigation.

Process Based Regulations

The new regulations also implement important changes to certain procedural aspects of the CON law and regulations. Under the new regulations, anyone wishing to oppose a proposed new project must do so within sixty days of the review period, unless expedited review of the application is granted, in which case any opposition is due within thirty days. Additional flexibility is built into the new regulations for the completion date of construction projects, and other important procedural changes are met. The new regulations also clarify when a CON may be revoked. Importantly, the failure of a provider to incur a capital expenditure within the initial twelve-month implementation period through initiation of substantial above ground project construction or the purchase of proposed equipment now may lead to revocation. Department Rule 111-2-2-.05(f).

Withdrawn Proposed Regulations

Of interest also are the proposed regulations that did not become final. The Department had proposed significant revisions to the regulations respecting the submission of LNR requests for physician owned, single specialty ambulatory surgical centers. Those proposed regulations generated intense debate and controversy in the provider community. As a result of that continuing debate, those proposed regulations have been withdrawn.

The Department also decided not to adopt its proposed new regulations defining what is indigent care. Under the proposed and now withdrawn new definition, indigent care would have meant revenue forgone for services to income tested patients whose individual or family income is less than or equal to 25 percent of the Federal Poverty Guidelines. However, foregone revenue would only qualify as such if the patient and treatment had been classified as such at the time of admission, before treatment, upon discharge or prior to billing. In no case could a hospital bill for services rendered and then turn around and count the foregone revenue as indigent care. This regulation sparked significant comment and was not adopted pending further debate and consideration. The Department also withdrew its proposed requirement that any health care facility provide indigent care at a level of three percent of its adjusted gross revenues in order to be considered reasonably financially accessible as required by the statute.

Summary

The CON law in Georgia is not without controversy. Routinely there are persons who advocate for its substantial modification or repeal. There are important issues debated respecting whether the CON law meets its goal of ensuring the efficient provision of cost effective and high quality health care, or creates inefficiencies and unreasonable entry barriers and anticompetitive effects. Regardless of the merits of that debate, the Department has made it clear that it intends to enforce the CON statute as written for as long as it remains the law in Georgia. The new regulations certainly clarify some important issues that have spurred much controversy and dispute in Georgia. Other areas of significant interest and the source of substantial controversy remain untouched, however. For any provider of healthcare services in Georgia, it is incumbent that they familiarize themselves with the scope of the CON statute and the new regulations. The foregoing is simply an overview of some of the most significant new regulations; consultation with an adviser or counsel who is closely familiar with those regulations is essential for any provider to operate properly in this regulatory environment.❑

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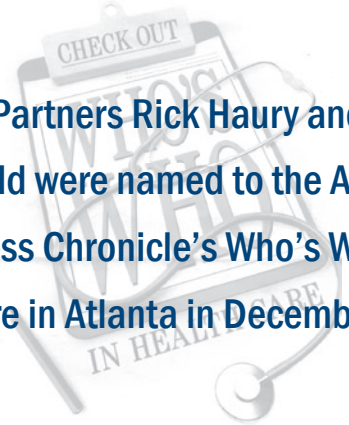

MMM Partners Rick Haury and Bob Threlkeld were named to the Atlanta Business Chronicle's Who's Who in Healthcare in Atlanta in December 2004

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Healthcare Update

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