

# **Illinois Hospital Association Small and Rural Membership Meeting**

**March 5, 2008**

## ***Legal Developments Affecting Small and Rural Hospitals***

Michael R. Callahan  
Katten Muchin Rosenman LLP  
525 W. Monroe . Chicago, Illinois  
312.902.5634  
Michael.callahan@kattenlaw.com

## Goals of Presentation and Discussion

- Review and discuss Stark II, Phase III final proposed rules as they affect physician recruitment activities
- The new Joint Commission Medical Staff Standards
- Negligent Credentialing Developments – Frigo v. Silver Cross Hospital (2007)
- Peer Review Confidentiality

## **Stark Act**

---

- The Federal Self-Referral Statute, commonly referred to as the “Stark Law”, provides that a physician cannot:
  - Refer Medicare patients to an entity
  - For the furnishing of designated health services (DHS)
  - If there is a financial relationship between the referring physician or an immediate family member and the entity
    - Unless an exception applies
  - Stark prohibits an entity from presenting a Medicare claim for a DHS that has been rendered pursuant to a prohibited referral

## **Stark Act** (cont'd)

---

- Penalties for violating Stark include:
  - Denial of claims
  - Monetary penalties of up to \$15,000 for each claim submitted as a result of a prohibited referral
  - A fine of up to twice the amount paid for the service
  - Exclusion from Medicare/Medicaid programs

## **Stark Act** (cont'd)

---

- “Financial relationship” includes four different types of relationships between a physician and an entity furnishing DHS:
  - Direct ownership or investment interest
  - Indirect ownership or investment interest
  - Direct compensation arrangement
  - Indirect compensation arrangement
- A physician who has any of the foregoing relationships with a DHS provider cannot refer Medicare or Medicaid patients unless an exception applies

## **Physician Recruitment and Retention – General Rule Under Stark**

---

- The Stark recruitment exception protects remuneration provided by a hospital to recruit a physician that is paid directly to the physician or through the group and that is intended to induce the physician to relocate his or her medical practice (or for new physicians to locate) to the geographic area served by the hospital in order to become a member of the hospital's medical staff
- General Requirements:
  - The arrangement is set out in writing and signed by all parties, which may need to include the physician group and the physician

## **Physician Recruitment and Retention – General Rule Under Stark (cont'd)**

---

- The arrangement is not conditioned on the physician's referral of patients to the hospital
- The amount of remuneration under the arrangement is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician

## **Physician Recruitment and Retention – New, Revised and Additional Standards**

- Relocation
  - Physician must relocate his or her practice to the geographic area served by the hospital
    - Physician must move medical practice at least twenty five miles; or
    - Must establish that at least 75% of the physician revenues from services provided by physician to patients, including inpatients, are derived from services provided to new patients not seen or treated at prior medical practice site during the preceding three years measured on an annual basis (fiscal or calendar year)

## **Physician Recruitment and Retention – New, Revised and Additional Standards (cont'd)**

- For initial “start up” year, 75% test is satisfied if there is a reasonable expectation the practice will derive 75% of revenues from new patients not treated at prior practice during preceding three years
- Medical Staff Membership
  - Recruited physician cannot already be a member of the hospital’s medical staff
  - The fact that a physician may have been a courtesy or locum tenens member who had little or no activity is irrelevant

## **Physician Recruitment and Retention – New, Revised and Additional Standards (cont'd)**

- Recruited physicians cannot be prohibited from establishing staff privileges at other hospitals or from referring to other hospitals, even if these hospitals are competitors
  - “The exception does not prevent hospitals from imposing reasonable credentialing restrictions on physicians when they compete with the recruiting hospital. Such restrictions must not take into account the volume or value of referrals”
    - Statement is somewhat vague but suggests that restrictions can be imposed that would preclude ownership in a competing surgi center, for example. Need to see if this point is further clarified

## **Physician Recruitment and Retention – New, Revised and Additional Standards (cont'd)**

- Geographic area served by the hospital
  - Geographic area served by the hospital is defined as the area comprised of all of the contiguous zip codes from which hospital draws fewer than 75% of its in-patients (see discussion on rural hospital below)
    - Use to be the lowest number of contiguous zip codes
  - The term “contiguous zip codes” does not mean only zip codes that are contiguous to a zip code in which the hospital is located, but zip codes that are next to or contiguous to each other

## **Physician Recruitment and Retention – New, Revised and Additional Standards (cont'd)**

- Hospital should look at in-patient data to determine where patients live and then calculate lowest number of zip codes that touch at least one other zip code in which the in-patients reside
- If all of the contiguous zip code areas account for less than 75% of the hospital's in-patients, the hospital is limited to recruitment into those areas
- If a zip code area has, for example, only large office buildings or commercial district and has no patients, a hospital may recruit into this “hole” zip code

## **Physician Recruitment and Retention – New, Revised and Additional Standards (cont'd)**

- Rural Hospitals
  - Rural area means an area that is not an urban area. If you are being reimbursed as a rural hospital, you are rural for purposes of this Stark standard
  - “Geographic area served by hospital” means the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 90% of its inpatients

## **Physician Recruitment and Retention – New, Revised and Additional Standards** (cont'd)

- If the hospital draws less than 90% from all of the contiguous zip codes for inpatients, area may include non-contiguous zip codes beginning with where the highest percentage of hospital inpatients resides, and continuing to add non-contiguous zip codes in decreasing order of inpatient percentages.
- If a group practice is recruiting from a rural area or Health Professional Shortage Area (“HPSA”) for a new physician to replace a physician who retired, or relocated outside the area served by the hospital, or died, within the previous 12 months, the costs allocated by the practice cannot exceed either:

## **Physician Recruitment and Retention – New, Revised and Additional Standards** (cont'd)

- The actual additional incremental costs attributed to the physician or
- The lower of a per capita allocation or 20% of the groups aggregate costs
- Recruitment by a rural hospital to an area outside the hospital's geographic market is permitted if HHS determines in an advisory opinion that there is a demonstrated need in this area.

## **Physician Recruitment and Retention – New, Revised and Additional Standards** (cont'd)

- Retention payments in underserved areas – Written offer permitted if:
  - Physician received a bona fide written recruitment or employment offer by an entity or group unrelated to the hospital
  - Physician must move at least 25 miles and outside the geographic area served by the hospital
  - Any retention payment is subject to the same obligations and restrictions if any, as the original recruitment, forgiveness or employment offer

## **Physician Recruitment and Retention – New, Revised and Additional Standards** (cont'd)

- The retention payment does not exceed the lower of
  - The difference between the physician's current income from the income the physician would receive under the bona-fide offer over no more than a two year period or
  - The reasonable costs the hospital would incur to recruit replacement physician.
- Retention payments – no written offer
  - Physician must provide written certification detailing the offer, name of recruiting entity location, anticipated income and benefits, and

## **Physician Recruitment and Retention – New, Revised and Additional Standards** (cont'd)

- Hospital must take steps to verify the bona fide opportunity
- Retention payment under these circumstances, as opposed to when there is an actual bona fide offer
  - May not exceed the lower of
    - 25% of physician's current income or
    - The reasonable costs of recruiting a replacement for the retained physician

## **Physician Recruitment and Retention – New, Revised and Additional Standards (cont'd)**

- Retained physician practices in a rural area or HPSA or is an area of demonstrated need as per on advisory opinion
- At least 75% of the physician's patients reside in a medically underserved area or are members of a medically underserved population
- The hospital does not enter into a retention arrangement with a particular referring physician more than once every five (5) years
- Terms may not vary based on the amount of volume or value of services or referrals

## **Physician Recruitment and Retention – New, Revised and Additional Standards (cont'd)**

- If multiple configurations containing the same number of zip codes permit the hospital to meet the 75% (or 90% for rurals), hospital is entitled to use any of the configurations
- The date on which the 75% (or 90%) standard applies is the date on which the parties have signed the written recruitment agreement – recognizes that service areas may change with different recruitment arrangements
- Even if a hospital is part of a health system, the standard is hospital and not health system specific

## **Physician Recruitment and Retention – New, Revised and Additional Standards (cont'd)**

- Payment guaranty by group practice
  - A hospital may seek to have a physician group guaranty repayment of any monies advanced to the group on behalf of the recruited physician if, for example, physician does not fulfill community service requirement
  - It does not let the hospital off the hook from its obligation to go after the physician for breach of contract or other claims or failing to meet community service or other related obligations under the recruitment arrangement

## **Physician Recruitment and Retention – New, Revised and Additional Standards (cont'd)**

- Comments in the Federal Register make the particular point that hospitals are obligated to collect any amounts owed by the physician or the physician practice making the guaranty because if collections are not sought, this would be viewed as remuneration to the group practice or the recruited physician and would need to be analyzed under the Anti-Kickback Statute

## **Physician Recruitment and Retention – New, Revised and Additional Standards (cont'd)**

- Allocation of group practice costs to recruited physician
  - General rule is that a group practice may only take into account the “actual costs incurred by the . . . physician practice in recruiting a new physician . . .” when determining payment to the referred physician under an income guarantee
  - Stated differently, the group is not permitted to divide expenses on a pro rata basis among all physicians, including newly recruited physicians, if no additional expenses have been incurred

## **Physician Recruitment and Retention – New, Revised and Additional Standards** (cont'd)

- For example, if a physician joins a four person practice but no additional employees are hired, no new employee expenses have been incurred and therefore cannot be considered an incurred cost
- Actual costs incurred for recruitment efforts by the group such as head hunter fees, airfare, hotel, meals, costs associated with visits, moving expenses, telephone calls, tail insurance and other related expenses, can be included in the cost allocation assessment

## **Physician Recruitment and Retention – New, Revised and Additional Standards (cont'd)**

- A hospital may pay a physician group for time spent in the recruitment of a physician as long as the requirements of the reasonable compensation exception have been met.
  - It is irrelevant whether the recruited physician did or did not join the group for purposes of this exception
- Where recruited physician is replacing “a deceased, retiring, or relocating physician in an underserved area” the practice may, when calculating an income guarantee, use a per capita allocation of the practice’s aggregate overhead and other expenses as long as it does not exceed 20% of the practice’s aggregate cost or use the alternative method of allocating the actual additional incremental costs to the practice

## **Physician Recruitment and Retention – New, Revised and Additional Standards (cont'd)**

- Physician must join group practice
  - For the exception to apply, the recruited physician must be a physician in the group practice or a member of the group. The exception does not apply to a physician who simply leases space and equipment from the group at the same location. As a practical matter, the hospital cannot provide support to the group practice for this arrangement, including the use of income guarantees.

## **Physician Recruitment and Retention – New, Revised and Additional Standards (cont'd)**

- Practice Restrictions
  - In a major reversal, Stark II, Phase III now permits reasonable restrictions on a recruited physician's ability to practice medicine in the geographic area served by the hospital
  - Although not completely deferring to state and local laws regarding noncompete agreements, the commentary states that "we believe that any practice restrictions or conditions that do not comply with applicable State and local law run a significant risk of being considered unreasonable"

## **Physician Recruitment and Retention – New, Revised and Additional Standards (cont'd)**

- The result of this reversal is that hospitals and group practices may utilize different but reasonable practice restrictions including, but not limited to:
  - Restrictive covenants and non-compete clauses
  - Reasonable liquidated damages clauses
  - Restrictions on moonlighting
  - Prohibitions on soliciting patients and/or employees of the physician practice

## **Physician Recruitment and Retention – New, Revised and Additional Standards** (cont'd)

- Requiring that the recruited physicians treat Medicaid and indigent care patients
- Requiring that a recruited physician not use confidential or proprietary information of the physician practice
- Requiring that recruited physicians repay losses of his or her practice that are absorbed by the physician practice in excess of any hospital recruitment practice

## Other Changes Under Stark II, Phase III

- Recruited physicians not subject to relocation requirement
  - A resident or a physician who has been in practice for one year or less
  - Where it has been determined through an advisory opinion that the physician does not have an established medical practice that serves or could serve a significant number of patients who are or could become patients of the recruiting hospital
  - A physician who was employed on a full time basis for at least two years immediately prior to the recruitment arrangement by one of the following, as long as the physician did not have a private practice in addition to the full-time employment:

## **Other Changes Under Stark II, Phase III**

**(cont'd)**

- A Federal or State bureau of prisons or other similar entity, to serve the prison population
  - The Department of Defense or Department of Veteran Affairs to serve active or veteran military personnel and their families
  - An Indian Health Service facility
  - Recruitment of a physician outside the geographic area of a rural hospital is permitted if an advisory opinion is issued by the secretary demonstrating a need
- Recruitment exception has been extended to apply to federally qualified health centers and rural health clinics

## **Physician and Recruitment – General Rule Under the Anti-Kickback Statute**

- The Federal Anti-Kickback Statute, which is intent based, generally makes it illegal to knowingly and willfully offer, pay, solicit or receive any remuneration, directly or indirectly, in return for the referral of a patient or in exchange for arranging for an item or service payable, in whole or in part, under a federal health care program
- Violations are punishable by imprisonment, treble damages and fines of up to \$50,000

## **Physician and Recruitment – General Rule Under the Anti-Kickback Statute (cont'd)**

- Although the Anti-Kickback Statute has a safe harbor for physician recruitment, it is very narrowly drawn and only applies to a physician who has been practicing within his or her specialty for less than a year and relocates a primary practice within a defined health professional shortage area.
- Additional Safe Harbor Standards - The relevant safe harbors criteria include many of the same standards under Stark III. Additional requirements include the following:

## **Physician and Recruitment – General Rule Under Anti-Kickback Statute (cont'd)**

---

- Benefits which are provided cannot be in excess of a three year period and should not be renegotiated during the three year period in any substantial aspect
- Physician should not be restricted from obtaining medical staff privileges at or referring services to or otherwise generate any business from a competing entity including a hospital

## **Physician and Recruitment – General Rule Under the Anti-Kickback Statute (cont'd)**

---

- The physician should agree to treat Medicare/Medicaid and in-patients from other federal health programs in a non-discriminatory manner
- Other standards to incorporate
  - Where possible, hospital should engage in a community need/community benefit analysis to determine whether there is a specific need in the community, versus a specific need for the hospital, which will be served by the recruited physician in his or her specialty

## **Physician and Recruitment – General Rule Under the Anti-Kickback Statute (cont'd)**

- This analysis should be supported by hard statistical information, use of physician-patient ratios and other factors sometimes utilized in a needs assessment policy which can take into account factors such as splitters, age of physicians, waiting times, out migration patterns, underserved indigent, Medicaid and other patient populations, etc.
- All payment and support arrangements should always take into consideration prevailing fair market value standards in the area

## **Physician and Recruitment – General Rule Under the Anti-Kickback Statute (cont'd)**

- Any recruitment expenses paid, whether to the group or directly to the physician, should require bills, invoices and the like, where possible, these costs should be determined in advance to make sure that they are reasonable
- Any loans which are made should be consistent with bank industry standards, particularly as it relates to the use of promissory notes, security interests and other protections in the event that the physician defaults on a loan

## **Physician and Recruitment – General Rule Under the Anti-Kickback Statute (cont'd)**

- Where income guarantees are utilized, again, fair market value should prevail and hospital should be looking to such groups as MGMA, Sullivan Cotter or other similar industry standards
- Local pay scales obviously can be taken into consideration but should be documented. It is also important to make sure that the allocated cost standards under Stark III are factored into this analysis

## Questions

- For those physicians who are actively drawing funds, what happens if there is a remaining work off balance at the end of the term of their recruitment arrangement?
  - First of all, it is important to point out that the Anti-Kickback Statute limits support to a three year period. I note that the work off time frame for some appears to be 48 months. Are these 3 or 4 year arrangements or, for example, does the document represent a two year support period followed by up to a two year work off time frame?

## Questions (cont'd)

- Part of the problem appears to be that physicians are not actively pursuing the identified work off activities set at \$150 per hour. One question is whether there are sufficient options for them to utilize or if additional work off opportunities can be identified.
- As a general rule, the standards prohibit revising a contract during the term of the agreement until at least one year has expired at which point, if it needs to be revised, it must be terminated and then a new contract drafted. In this instance, it might not be necessary but we would need to see the original contracts in questions.

## Questions (cont'd)

- If there is still a remaining work off balance at the end of the term, it either needs to be paid or a new arrangement created that extends the work off for a limited period of time or converts the amount to a loan which must be paid back. The hospital is not able to simply write these dollars off and must find an appropriate way of dealing with these balances.
- These concepts apply equally to those physicians who are in a pay off period.

## Questions (cont'd)

- Can the hospital recruit a physician for a specific town or community as opposed to a physician who will tend to the needs of the hospital's service area?
  - As long as the specific town or community, is within the 75% geographic market, recruitment for this town is acceptable. We would assume that the physicians will also accept patients from other towns.
- Can the hospital enter into an agreement with the group or must it be with a new physician?
  - Hospital has the flexibility of contracting either with the group or with the recruited physician.

## Questions (cont'd)

If hospital contracts with the group, the allocation of expense standard discussed above needs to be followed. Also, hospital must make sure that the support flows through the group to the physician, usually in the form of an income guarantee.

- What is the length of support which a hospital can provide to the group/recruited physician and can repayment of any due amounts be beyond this initial term?
  - As per the previous comments, hospital should not be providing benefits in excess of a three year period. Therefore, a draw period of one, two or three years is acceptable.

## Questions (cont'd)

Repayment of any due amounts would be treated as a separate time frame and is not really an extension of support. If the hospital wishes to provide a one year repayment period for every year of draw, this would be acceptable.

- Can the hospital reduce its support if the physician gets on the medical staff of another hospital?
  - Both Stark and the Anti-Kickback Statute prohibit a recruiting hospital from limiting where a medical staff physician can obtain privileges or otherwise practice.

## Questions (cont'd)

We interpret this to be different from reducing support if the physician does obtain privileges elsewhere. The issue would be what level of reduction is the hospital considering. If the reduction is significant enough so as to preclude the physician from getting privileges at another hospital, this would probably be viewed as a violation of the standard.

## Questions (cont'd)

- Can the hospital and/or physician group impose practice restrictions as a condition of receiving support?
  - As discussed previously, Stark now allows the imposition of reasonable practice restrictions as a condition of receiving recruitment support. These limitations can be imposed by both the group and the hospital. Moreover, the new rule also allows the hospital to place credentialing restrictions on a recruited physician if they engage in direct competition with the hospital.

## Questions (cont'd)

- What expenses can be allocated by the group for purposes of a recruited physician?
  - This question has been previously discussed. Again, the general rule is that only those expenses incurred as a result of the new recruited physician can be taken into consideration as part of the income guaranty formula. Expenses cannot be divided or taken into account on a pro rata basis. The exception is where the physician is replacing a retiring, deceased or relocating physician in an underserved area.

## Questions (cont'd)

- Can the hospital support a second physician if the group is still paying off the first physician?
  - As long as the requirements under Stark and the Anti-Kickback Statute are met, it is not impermissible to support a second physician. An additional question would be whether the same level of support can be provided depending on community need/benefits and other analyses.

## Questions (cont'd)

- If a physician who is newly recruited to an existing group decides to leave that practice, can the hospital support the new recruit in his own practice for the remainder of time?
  - First, I would suggest you weigh the political and legal implications of the physician who leaves the practice. Because Stark III will now allow the imposition of a restrictive covenant, the physician might not be allowed to practice within the market.
  - Second, if there is no such restriction and politics aside, you would then want to determine the legal impact of the physician's decision to leave the group.

## Questions (cont'd)

Ideally, you will not have to cover any penalty or dollars owed to the group by the recruited physician. This burden should be on the physician and not the hospital, although it possibly could be factored into a new support arrangement. This would have to be examined on a case-by-case basis. Moreover, you would need to enter into a new agreement rather than continue the old agreement which probably went through the practice group, even though the terms might be the same, if not identical.

## Questions (cont'd)

- May the hospital and/or the physician group require participation in the IPA or the PHO?
  - I believe a requirement that obligates the physician to participate in the IPA and/or PHO would be reasonable.
- Can the hospital support a solo start up?
  - Yes, the question I would have is whether a solo practitioner can reasonably survive in your market.

## Questions (cont'd)

- Can the hospital extend the pay back period?
  - Because the hospital is obligated to collect these amounts, whether voluntarily or not, extension of the pay back period, with interest, would be permissible.
- What if a physician with a remaining balance is subsequently employed by the hospital?
  - The hospital will have to find some way to recover these monies whether by physician pay off, a salary reduction from a fair market value salary that otherwise would be payable to this physician, or through some other means.

## Questions (cont'd)

The hospital would need to carefully document this so as to not appear that they are inflating the salary so as to cover the amounts truly owed to the hospital.

- Is a \$150 draw work off credit legitimate market value?
  - Yes.
- If the identified deficit has been in the hospital service area but not specifically in the town where the hospital is located Libertyville, can the hospital support a surgeon in the town?
  - It depends. You would have to look at where the

## Questions (cont'd)

- The specific need is and whether a surgeon located in and around the town would reasonably draw from the area of need as part of the Libertyville service area. For example, the service area of most primary care physicians is smaller than compared to a general surgeon or a cardiologist. There would be no particular problem under Stark III, but because under the Anti-Kickback Statute, you most likely will need to show a community need or community benefit. If there is absolutely no overlap between the town where the hospital is located and the identified area of community need, it would probably be difficult to support a recruitment arrangement

## Questions (cont'd)

particularly if most people would agree that patients in this area are not likely to travel to town for services. This would have to be evaluated on a case-by-case basis.

- Can the hospital participate in joint marketing/advertising of a recruited physician?
  - If the marketing/advertising campaign benefits both the hospital and the recruited physician on an equal basis, however determined, it would be appropriate and in fact required that the physician or group practice pay its equal share of these expenses.

## Questions (cont'd)

- The hospital should not subsidize these expenses and should instead require a 50/50 payment arrangement for any physician supported irrespective of language and nationality - the hospital is not required to provide these services for all but again, any such support ideally should be tied to where there is an identified need.
- What about educational support to physicians?
  - Hospital may provide items or services, not including cash and cash equivalents, up to an aggregate of \$329 per year per physician if not made to induce referrals.

## Questions (cont'd)

This support can include educational sessions, such as coding seminars or any other services up to the \$329 per year limit. There also is a medical staff incidental benefit standard which allows items and services, again excluding cash and cash equivalents, to physicians as long as the item is used on campus and is reasonably related to the provision of medical services, of less than \$25 per physician.

## Questions (cont'd)

- Can a hospital fix a purchase price that would be payable at a future date or does the practice have to be valued at the time of the actual purchase?
  - As a general rule, the practice has to be valued at the time of the purchase. If the practice, for example, had decreased appreciably in a two year time frame, a hospital would be overpaying and this would trigger anti-kickback and other problems.

## Questions (cont'd)

- What about computer EMR assistance?
  - There is a Stark Act exception to electronic health record items and services that applies to non-monetary remuneration (consisting of items and services in the form of software or IT and training services, but not hardware) “necessary and used predominantly” to create, maintain, transmit or receive EHR, provided that a number of conditions be satisfied.

## Questions (cont'd)

There are numerous requirements in order to comply with this exception as it relates to this physician recruitment discussion, including an obligation that a physician must pay 15% of the hospital's cost for items and services. The hospital is not allowed to finance physician's payment or loan funds in order to pay for these items and services. We have examined this exception for a number of clients who are implementing EMR/EHR systems and would gladly provide more detail at a different date.



***JOINT COMMISSION  
MEDICAL STAFF STANDARDS***

## Focused and Ongoing Performance Monitoring

- Standard 3.10
  - Performance improvement. Medical staff is **actively** involved in measurement, assessment and improvement of the various PI standards.
  - Medical Staff is now a provider of oversight for quality of care services and treatment.
  - Is responsible for ongoing evaluation of competency and delineation of privileges.

## Focused and Ongoing Performance Monitoring (cont'd)

- Standards MS.4.10 through MS.4.45
  - MS.4.10 through 4.45 have been significantly rewritten.
  - The purpose of these Standards is to establish additional evidence-based processes to determine a practitioner's competency.
  - With regard to privileging, the new Standard imposes a higher burden in determining whether the applicant or current medical staff physician has the degree of training, education and experience required to perform each of the requested privileges and procedures.

## Focused and Ongoing Performance Monitoring (cont'd)

- Health status of practitioner can be confirmed by personnel at another hospital at which the applicant holds privileges or by a currently licensed physician approved by the organized medical staff. (MS.4.15, EP4 (See Note))
- With respect to the issue of privilege decision notification, in the case of denial, the applicant must be informed of the reason for denial (MS.4.25 EP2) – This requirement already exists in Illinois which also requires an explanation at the pre-application stage. Could be interpreted to apply to pre-application procedures as well.
- Notice obligation also requires that the physician be made aware of any fair hearing rights, to the extent available – does not require a hearing for the denial of initial applicants. (MS.4.25, EP4). (Note that the Joint Commission does not require hearings for termination of temporary privileges.)

## Focused and Ongoing Performance Monitoring (cont'd)

- Information about a practitioner's scope of privileges must be updated as changes in clinical privileges are made.
- Medical staff and governing board must develop criteria that will be considered when deciding to grant, limit or deny requested privileges – ties in with CMS Conditions of Participation and concerns about use of core privileging not related to actual evidence-based privileging.
- If privileging is unrelated to quality of care, treatment and services or professional competence, evidence must exist that impact of resulting decisions on the quality of care, treatment, and services is evaluated – addresses issue of economic credentialing?

## Focused and Ongoing Performance Monitoring (cont'd)

- Emphasis is on three new concepts
  - General Competencies
    - Patient care (compassionate, appropriate, effective)
    - Medical/clinical knowledge (demonstrated knowledge and application of biomedical, clinical and social services)
    - Practice-based learning and improvement (is physician obtaining CMEs) (use of scientific evidence and methods to investigate, evaluate and improve practices)

## Focused and Ongoing Performance Monitoring (cont'd)

- Interpersonal and communications skills (demonstration of interpersonal and communication skills to establish and maintain professional relationships)
- Professionalism (commitment to continuous professional development, ethical practice, reactivity to diversity and a reasonable attitude)
- Systems-based practice (is physician abiding by all policies, participating in EHR initiatives, modifying behaviors based on profiling data)

## Focused and Ongoing Performance Monitoring (cont'd)

- Looks for a balance between clinical and professional behavior
- Focused Professional Practice Evaluation (“FPPE”)
- Ongoing Professional Practice Evaluation (“OPPE”)

## Focused and Ongoing Performance Monitoring (cont'd)

- MS.4.30 – Focused Professional Practice Evaluation
  - Standard expects the medical staff to identify and implement a method of evaluating practitioners without current performance documentation at the hospital, whether the physician is new or is an existing physician seeking new privileges, including processes where quality of care concerns arise, criteria for extending the evaluation period, and for communicating and acting on the results of the evaluation.
  - Need adequate information to confirm competence.
  - Core privileging.

## Focused and Ongoing Performance Monitoring (cont'd)

- Effective January 1, 2008, a period of focused professional evaluation is implemented for all initially requested privileges.
- A period of focused professional practice evaluation is implemented for all initially requested privileges (EP1).
  - Must develop criteria to evaluate performance of physicians when issues affecting patient safety and quality of care are identified (EP2).
  - Performance monitoring includes:
    - Criteria
    - Method for setting up a monitoring plan
    - Method for identifying duration of the plan
    - Identifying circumstances when an outside review will be sought (EP3).

## Focused and Ongoing Performance Monitoring (cont'd)

- Evaluation consistently applied (EP4).
- Focused review triggers are defined (EP5).
- Need to focus on the particular issue or privileges in question to make sure physician is currently competent to exercise same. Cannot avoid review simply because physician has no problems with other privileges (EP6).
- Must develop standard and criteria for determining what form of monitoring is to take place (EP7).
- How is resolution of performance defined – results or timing? (EP8)
- Resolution standard uniformly applied (EP9).

## Focused and Ongoing Performance Monitoring (cont'd)

- Would require “performance monitoring” particularly for those new physicians who have yet to establish a track record with the hospital or when questions about competency or ability are raised.
- Methods of focused professional practice evaluation can include, but are not limited to chart review, monitoring, clinical practice patterns, simulation, proctoring, external peer review, and discussion with other individuals involved in patient’s care. (Rationale for MS.4.30)
- All accumulated information from focus evaluation process must be integrated into performance improvement activities (Id).

## Focused and Ongoing Performance Monitoring (cont'd)

- MS.4.40 – Ongoing Professional Practice Evaluation.
  - Under the ongoing professional practice evaluation, here is a heightened emphasis on evaluating a physician's practice so as to identify trends that impact on quality of care and patient safety. Such criteria can include but are not limited to, the following:
    - Review of operative and other clinical procedures performed and their outcomes;

## Focused and Ongoing Performance Monitoring (cont'd)

- Pattern of blood and pharmaceutical usage;
  - Request for test and procedures;
  - Length of stay patterns;
  - Morbidity and mortality data;
  - Practitioners usage of consultants;
  - Other relevant criteria.
- Ongoing evaluation must be factored into any decisions to maintain, revise or revoke privileges.

## Focused and Ongoing Performance Monitoring (cont'd)

- Problems identified during ongoing review should trigger a focused review or other intervention. Generally looking for patterns or trends.
- “Ongoing” does not mean once a year.
- Medical Staff Bylaws must evidence how the staff will evaluate and act upon a report of concerns relating to a practitioner’s clinical practice and/or competence and further, that the concerns are uniformly investigated and addressed.

## Focused and Ongoing Performance Monitoring (cont'd)

- Evaluation can be based on different sources of information such as chart reviews, direct observation, monitoring, consultations with other care givers, etc.
- Must have a clearly identified process to facilitate evaluation of each physician (EP1).
- Data to be collected is determined by each department and approved by the organized medical staff (EP2).
- Information from ongoing performance monitoring is used to continue, revoke or limit any or all existing privileges (EP3).

# ***NEGLIGENT CREDENTIALING DEVELOPMENTS***

## Doctrine of Corporate Negligence

- Hospital, along with its medical staff, is required to exercise reasonable care to make sure that physicians applying to the medical staff or seeking reappointment are competent and qualified to exercise the requested clinical privileges. If the hospital knew or should have known that a physician is not qualified and the physician injures a patient through an act of negligence, the hospital can be found separately liable for the negligent credentialing of this physician.

## Doctrine of Corporate Negligence (cont'd)

- Evidence of whether a hospital and medical staff has satisfied its duty is based, in part, on whether they have followed licensing regulations, accreditation standards, bylaws and policies.

## **Standards on Which Claim Will Be Based**

- Joint Commission
- HFAP
- Hospital Licensing Act
- Medicare Conditions of Participation
- Hospital Corporate Bylaws and Policies
- Medical Staff Bylaws and Policies
- Comparison of Physician's Treatment to Standard of Care

## Examples of Negligent Credentialing Cases

---

- Darling v. Charleston Community Memorial Hospital (1965)
  - First case in the country to apply the Doctrine of Corporate Negligence.
  - Case involved a teenage athlete who had a broken leg with complications and was treated by a family practitioner.
  - Leg was not set properly and patient suffered permanent injury.
  - Hospital claimed no responsibility over the patient care provided by its staff physician.
  - Plaintiff argued that physician was unqualified to treat the patient.

## Examples of Negligent Credentialing Cases (cont'd)

---

- Court rejected this position as well as the charitable immunity protections previously provided to hospitals.
- Part of the basis for the decision was the fact that hospital was accredited by the Joint Commission and had incorporated the Commission's credentialing standards into its corporate and medical staff bylaws.

## Examples of Negligent Credentialing Cases (cont'd)

---

- These standards reflected an obligation by the medical staff and hospital to make sure physicians were qualified to exercise the privileges granted to them.
- The medical staff and hospital's decision to give privileges to treat patients with complicated injuries to an unqualified practitioner directly caused the patient's permanent injuries. Therefore, the hospital was held liable for the damages.

## Examples of Negligent Credentialing Cases (cont'd)

---

- Frigo v. Silver Cross Hospital (Ill. App. Ct., 2007)
  - Frigo involved a lawsuit against a podiatrist and Silver Cross.
  - Frigo alleged that podiatrist's negligence in performing a bunionectomy on an ulcerated foot resulted in osteomyelitis and the subsequent amputation of the foot in 1998.

## Examples of Negligent Credentialing Cases (cont'd)

---

- The podiatrist was granted Level II surgical privileges to perform these procedures even though he did not have the required additional post-graduate surgical training required in the Bylaws as evidenced by completion of an approved surgical residency program or board eligibility or certification by the American Board of Podiatric Surgery at the time of his initial appointment in 1992.

## Examples of Negligent Credentialing Cases (cont'd)

---

- At the time of his reappointment, the standard was changed to require a completed 12 month podiatric surgical residency training program, successful completion of the written eligibility exam and documentation of having completed 30 Level II operative procedures.
- Podiatrist never met these standards and was never grandfathered. In 1998, when the alleged negligence occurred, he had only performed six Level II procedures and none of them at Silver Cross.

## Examples of Negligent Credentialing Cases (cont'd)

---

- Frigo argued that because the podiatrist did not meet the required standard, he should have never been given the privileges to perform the surgery.
- She further maintained that the granting of privileges to an unqualified practitioner who was never grandfathered was a violation of the hospital's duty to make sure that only qualified physicians are to be given surgical privileges. The hospital's breach of this duty, she argued, caused her amputation because of podiatrist's negligence.

## **Examples of Negligent Credentialing Cases** (cont'd)

---

- Trial and appellate courts upheld a jury verdict of \$7,775,668.02 against Silver Cross.
- Podiatrist had previously settled for \$900,000.00.
- Illinois Supreme Court deemed the petition for leave to appeal.

## **Examples of Negligent Credentialing Cases** (cont'd)

---

- Lessons Learned
  - Must know and understand all accreditations, licensure, Medicare CoPs and case law obligations.
  - These obligations must be reflected in Hospital's corporate and medical staff bylaws and policies.
  - Criteria should be uniformly applied.
  - If you deviate from the criteria, explain why and/or consider grandfathering.

## Examples of Negligent Credentialing Cases (cont'd)

---

- Make free use of remedial actions which do not trigger fair hearings
  - Probation
  - Concurrent and retrospective reviews
  - Monitoring
  - Proctoring
  - Mandatory consultations that do not require prior approvals
  - Voluntary relinquishment of privileges
  - Continuing education and training
  - Is some form of impairment involved?

## Examples of Negligent Credentialing Cases (cont'd)

---

- Courts and juries are less likely to rule against a hospital where at least some form of corrective or remedial action was taken as opposed to where nothing was done.
- Plaintiffs are not entitled to confidential peer review information but can find out what remedial action, if any, was taken.
- Another issue in Frigo to consider is that the trial court ruled that the Medical Studies Act prohibited the introduction of peer review information to establish that hospital had met its duty of care – Silver Cross wanted to show that quality assurance and peer reviews over six years established that podiatrist had good outcomes, no complaints and was qualified to exercise surgical privileges.

# ***PEER REVIEW CONFIDENTIALITY***

## **Steps to Maximize Confidentiality Protection Under The Medical Studies Act**

- The relevant provisions of the Medical Studies Act are as follows:
  - All information, interviews, reports, statements, memoranda, recommendations, letters of reference or other third party confidential assessments of a health care practitioner's professional competence, or other data of health maintenance organizations, medical organizations under contract with health maintenance organizations or with insurance or other health care delivery entities or facilities, physician-owned insurance companies and their agents, committees of ambulatory surgical treatment centers or post-surgical recovery centers or their medical staffs, or committees of licensed or accredited hospitals or their medical staffs, including Patient Care Audit Committees, Medical Care Evaluation Committees, Utilization Review Committees, Credential Committees and Executive Committees, or their designees (but not the medical records pertaining to the patient), used in the course of internal quality control or of medical study for the purpose or reducing morbidity or mortality, or for improving patient care or increasing organ and tissue donation, shall be privileged, strictly confidential and shall be used only for medical research, the evaluation and improvement of quality care, or grating, limiting or revoking staff privileges or agreements for services, except that in any health maintenance organization proceeding to decide upon a physician's services or any hospital or ambulatory surgical treatment center proceeding to decide upon a physician's staff privileges, or in any judicial review of either, the claim of confidentiality shall not be invoked to deny such physician access to or use of data upon which such a decision was based. (Source: P.A. 92-644, eff. 1-1-03.)
  - Such information, records, reports, statements, notes, memoranda, or other data, shall not be admissible as evidence, nor discoverable in any action of any kind in any court or before any tribunal, board, agency or person. The disclosure of any such information or data, whether proper, or improper, shall not waive or have any effect upon its confidentiality, nondiscoverability, or nonadmissibility

## Steps to Maximize Confidentiality Protection Under The Medical Studies Act (cont'd)

---

- It is important for all medical staff leaders and the hospital to know the language and interpretation of the Medical Studies Act.
- As a general rule, courts do not like confidentiality statutes which effectively deny access to information.
- Although appellate courts have upheld the Medical Studies Act on numerous occasions, trial courts especially look for ways to potentially limit its application and will strictly interpret the statute.
- The courts have criticized attorneys for simply asserting the confidentiality protections under the Act without attempting to educate the court about what confidentiality and peer review is or explaining why the information in question should be treated as confidential under the act.
- One effective means of improving the hospital and medical staffs odds is to adopt a medical staff bylaw provision or policy which defines “peer review” and “peer review committee” in an expansive manner while still consistent with the language of the Act. Examples are set forth below:

## Peer Review:

- “Peer Review” refers to any and all activities and conduct which involve efforts to reduce morbidity and mortality, improve patient care or engage in professional discipline. These activities and conduct include, but are not limited to: the evaluation of medical care, the making of recommendations in credentiality and delineation of privileges for Physicians, LIPs or AHPs seeking or holding such Clinical Privileges at a Medical Center facility, addressing the quality of care provided to patients, the evaluation of appointment and reappointment provided to patients, the evaluation of appointment and reappointment applications and qualifications of Physicians, LIPs or AHPs, the evaluations of complaints, incidents and other similar communications filed against members of the Medical Staff and others granted clinical Privileges. They also include the receipt, review, analysis, acting on and issuance of incident reports, quality and utilization review functions, and other functions and activities related thereto or referenced or described in any Peer Review policy, as may be performed by the Medical Staff or the Governing Board directly or on their behalf and by those assisting the Medical Staff and Board in its Peer Review activities and conduct including, without limitation, employees, designees, representatives, agents, attorneys, consultants, investigators, experts, assistants, clerks, staff and any other person or organization who assist in performing Peer review functions, conduct or activities.

## Peer Review (Cont'd)

- “Peer Review Committee” means a Committee, Section, Division, Department of the Medical Staff or the Governing Board as well as the Medical Staff and the Governing Board as a whole that participates in any Peer Review function, conduct or activity as defined in these Bylaws. Included are those serving as members of the Peer Review committee or their employees, designees, representatives, agents, attorneys, consultants, investigators, experts, assistants, clerks, staff and any other person or organization, whether internal or external, who assist the Peer Review Committee in performing its Peer Review functions, conduct or activities. All reports, studies, analyses, recommendations, and other similar communications which are authorized, requested or reviewed by a Peer Review Committee or persons acting on behalf of a Peer Review Committee shall be treated as strictly confidential and not subject to discovery nor admissible as evidence consistent with those protections afforded under the Medical Studies Act. If a Peer Review Committee deems appropriate, it may seek assistance from other Peer Review Committees or other committees or individuals inside or outside the Medical Center. As an example, a Peer review Committee shall include, without limitation: the MEC, all clinical Departments and Divisions, the Credentials Committee, the Performance Improvement/Risk Management Committee, Infection Control Committee, the Physician’s Assistance Committee, the Governing Board and all other Committees when performing Peer Review functions, conduct or activities.