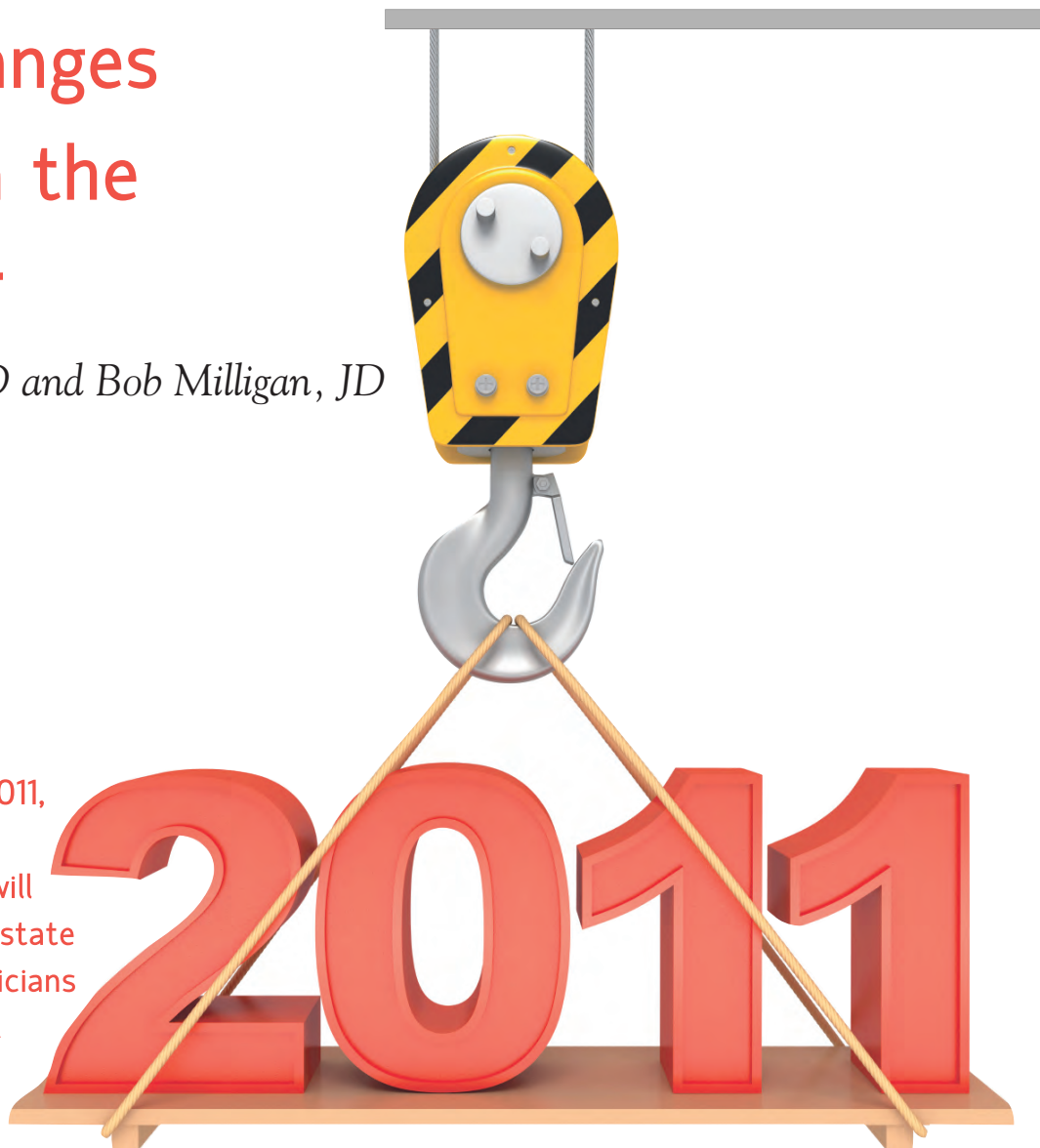


# Legal Changes to Ring in the New Year

By: Ken Briggs, JD and Bob Milligan, JD



Beginning January 1, 2011, certain Arizona healthcare providers will have new federal and state laws to observe. Physicians who refer government program patients to their own practices

for certain MRI, CT or PET services will need to make patients aware of alternative suppliers of those services. Also going into effect over the New Year are substantial changes to the state laws regulating Physician Assistants. This article provides an overview of these recent changes and suggests some practical considerations for implementing the changes.

## ***I. Yet Another Element for the In-Office Ancillary Services Exception to the Stark Law***

The physician self-referral law, commonly known as the Stark law, prohibits physicians from referring government program patients in need of “designated health services” to facilities with which the physician has a financial relationship, unless an exception applies. One of the most widely used and complex exceptions is the in-office ancillary services (IOAS) exception.<sup>1</sup> This exception permits referrals to the referring physician’s practice, as long as the requirements of

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the exception are met. Section 6003 of the Patient Protection and Affordable Care Act adds yet another requirement to the IOAS exception, effective January 1, 2011. Basically, the new requirement obligates physicians who make referrals for certain

MRI, CT or PET imaging services (those listed as designated health services on the list of CPT/HCPCS Codes) to notify patients of local alternative suppliers of the service, at the time the referral is made. Proponents of the requirement believe

it will reduce the ability of physicians to profit improperly from referrals made pursuant to the IOAS exception, by bringing transparency into the referral process.

Rules issued by the Center for Medicaid and Medicare Services (CMS) state that the disclosure document must list the name, phone number and address of at least five alternative suppliers of the imaging service within a 25-mile radius of the physician's office. The notice must be written in a manner that can be reasonably understood by all patients. In addition, the disclosure notice must be presented to the patient each time a referral is made for a service that triggers the requirement, i.e. a patient who needs serial studies must be given a copy of the notice each time the study is ordered.

The law requires that at least five suppliers be listed on the disclosure. If there are less than five alternative suppliers of the service within a 25-mile radius of the referring physician's office, then the disclosure must list all of the alternative suppliers. Hospitals are not included in the definition of "supplier."

Because this requirement is an element of the IOAS exception to the Stark law, the requirement applies only to those referrals that are made pursuant to the IOAS exception. For example, the disclosure requirement is not triggered where a radiologist orders diagnostic radiology services pursuant to a consultation initiated by another physician, because under these circumstances the radiologist's request is not considered a referral for Stark purposes.

Implementing the disclosure requirement into the daily operation



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of your medical practices may be the most burdensome element of the new requirement. Developing a process to alert the referring physician when the disclosure is needed is essential, because liability under the Stark law can be catastrophic. The Stark law is a

will go into effect on New Year's Day.<sup>2</sup> These changes were enacted by House Bill 2021, which amends sections 32-2501, 32-2504 and 32-2521, and repeals section 32-2524 of the Arizona Revised Statutes.

physician so long as it is "within the physician assistant's skills, is within the physician's scope of practice and is supervised by the physician."<sup>4</sup>

The scope of responsibility for the physician supervising the PA also is

"At present, there is no requirement that the disclosure document be maintained in the patient's medical record. CMS has suggested noting that the fact of the disclosure in the patient's chart. Practices should develop and adhere to policies for using the disclosure form as required, and for documenting its use. Establishing these policies will make it much easier to demonstrate compliance in the event of a patient complaint or an audit."

Ken Briggs, JD and Bob Milligan, JD

strict liability law, which means that even technical violations of the law will expose the referring physician and his or her practice to liability.

Also, documenting compliance with the requirement will be important. At present, there is no requirement that the disclosure document be maintained in the patient's medical record. CMS has suggested noting that the fact of the disclosure in the patient's chart. Practices should develop and adhere to policies for using the disclosure form as required, and for documenting its use. Establishing these policies will make it much easier to demonstrate compliance in the event of a patient complaint or an audit.

## **II. Sweeping Changes to the Laws Affecting Arizona Physician Assistants**

Substantial changes to the laws affecting physician assistants (PAs) and their supervising physicians also

HB 2021 clarifies the scope of practice of PAs and makes changes to the process for documenting that scope. The PA's scope of practice is clarified by explicitly stating that the "physician assistant may perform those duties and responsibilities, including the ordering, prescribing, dispensing and administration of drugs and medical devices that are delegated by the supervising physician."<sup>3</sup>

If the PA has prescribing authority, then the PA must submit a Prescribing Authority form to the AZBoPA when there are any changes to the scope of the delegated authority, or when there is a change in the identity of the supervising physician(s). In addition, the PA must file a Prescribing Authority form with the Board if the PA did not have a Notice of Supervision form on file with the Board or before December 31, 2010. HB 2021 makes it explicit that a PA may provide any medical service that is delegated by the supervising

clarified.<sup>5</sup> A supervising physician may supervise up to four PAs at the same time, but the supervision for each PA must be continuous. If the supervising physician is not routinely present at the PA's practice location, then the team must meet once each week by person or telecommunication "to ensure ongoing direction and oversight of the physician assistant's work."<sup>6</sup> To demonstrate that this oversight is routinely taking place, the physician/PA team should document the time the meeting or discussion took place, the subject matter of the discussion, and whether the discussion was in-person or via telephone.

The Board also requires the physician/PA team to ensure that the professional relationship between the two healthcare providers is clarified in four ways. Each physician-physician assistant team must ensure that:

1. The physician assistant's scope of practice is identified.

2. The delegation of medical tasks is appropriate to the physician assistant's level of competence.
3. The relationship of, and access to, the supervising physician is defined.
4. A process for evaluation of the physician assistant's performance is established.<sup>7</sup>

There is no requirement to document these elements but absent a written agreement between the parties, resolving potential disputes arising from confusion of the PA's scope of practice may prove arduous.

As of the New Year, PAs are no longer required to file Notice of Supervision forms with the AZBoPA. However, a Delegation Agreement is

now required between a PA and each physician that supervises the PA. The agreement must be signed by both the PA and the supervising physician(s) and filed at the PA's practice location before the PA can perform healthcare tasks. The statutory language relating to the Delegation Agreement is as follows:

*The agreement must state that the physician will exercise supervision over the physician assistant and retains professional and legal responsibility for the care rendered by the physician assistant. The agreement must be signed by the supervising physician and the physician assistant and updated annually. The agreement must be kept on file at the practice site and made available to the board on request.<sup>8</sup>*

The Delegation Agreement is essentially an acknowledgement by

the PA and the supervising physician of the legal responsibilities associated with delegating and supervising healthcare tasks performed by another person. So long as there is an executed Delegation Agreement in place, any physician who has signed the Agreement is permitted to supervise the PA who signed the Agreement.

The broad language of A.R.S. §32-2531(H)(4), excerpted above, provides significant flexibility in the drafting of Delegation Agreements. For example, the provisions required by the new law could be incorporated into the PA's employment agreement; alternatively, these provisions could form a short, stand-alone agreement. Either way, because Delegation Agreements must be "updated annually," it will be important for the practice



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to calendar a reminder to ensure that this happens. Otherwise, the supervising physician and the PA could be in violation of Arizona law and subject to licensing board action.

### III. Conclusion

The IOAS exception and the sweeping changes to the laws affecting PAs must be carefully scrutinized by medical professionals and their employers to ensure that there is a system in place to implement the requirements into the daily practice of the professionals and to remind the practice to review and update the required documents as needed. The changes discussed in this article are relatively easy to implement into a medical practice. However, failing to implement these changes, or not reviewing the disclosure and Delegation Agreements when needed, could be costly both for the practice and for the medical professionals subject to the requirements. [ru](#)

#### Sources

1. 42 C.F.R. Section 411.355(b), available at [www.gpoaccess.gov/cfr/index.html](http://www.gpoaccess.gov/cfr/index.html).
2. See these guidelines published by the AZBoPA for a general overview of the new regulations: *Frequently Asked Questions*, [www.azpa.gov/PA%20Center/PAFAQCombined.pdf](http://www.azpa.gov/PA%20Center/PAFAQCombined.pdf); *Notice of Legislative Changes*, [www.azpa.gov/PA%20Center/PANoticeCombined.pdf](http://www.azpa.gov/PA%20Center/PANoticeCombined.pdf).
3. A.R.S. § 32-2531(B).
4. A.R.S. § 32-2531(D).
5. The "physician assistant is the agent of the physician assistant's supervising physician in the performance of all practice related activities including the ordering of diagnostic, therapeutic, and other medical services." A.R.S. § 32-2531(F).
6. A.R.S. § 32-2531(J).
7. A.R.S. § 32-2533(B).
8. A.R.S. § 32-2531(H)(4)



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