

Re: **New Stark II Rules**

Dear Sir or Madam:

We encourage our clients to regularly evaluate their business practices to ensure compliance with relevant statutes, laws and regulations. As you may know, Phase II of the Stark II self-referral regulations (hereinafter referred to simply as “Stark”) is expected to become effective on July 26, 2004. While responses to the public comment period may cause some minor “tweaking” of the Final Rule before it becomes effective, we do not expect that the Final Rule will significantly differ from the Interim Final Rule, which was published on March 26, 2004. As such we recommend that you become familiar with the Phase II changes and evaluate your current practices in light of those changes.

You should also be aware that changes to the Stark law may modify opinions that our firm has previously rendered. Therefore, if we have provided you with a Stark opinion letter in the past, you should consider contacting us to discuss whether changes to the law modify our interpretation of your particular practices and/or circumstances. The changes to the law may not affect your present practices, but in some cases, minor adjustments may be required to achieve compliance. For your reference we have briefly described a few of the changes to Stark below.

In-Office Ancillary Services Exception - The most significant Phase II Rule modification to this exception pertains to the location requirement. The former “same building” criterion has been replaced by three new tests, each of which requires some Of Counsel amount of non-DHS physician services to be offered and provided in the same building where DHS are furnished. We are dispensing with a detailed discussion of the tests here, not only for the sake of brevity, but also because some observers are hopeful that the Centers for Medicare and Medicaid Services (CMS) will clarify the tests even further in the Final Rule. The take-home message is that the Phase II changes should offer greater flexibility to physicians who already qualify (and those who would like to qualify) for the in-office ancillary services exception.

Percentage Compensation Arrangements - With respect to physician compensation, the Phase II Rule clarifies that certain percentage compensation arrangements will satisfy the “set in advance” requirement of several Stark exceptions. For example, if compensation *per unit* is set in advance but the aggregate compensation is not set in advance, the arrangement may still qualify for an exception.

Professional Courtesy - Phase II clarifies that free or discounted services provided to a physician or to his immediate family or office staff will not violate Stark, as long as certain requirements are met.

Nature of Financial Relationships - Phase II reemphasizes that any financial relationship between a referring physician and a DHS entity can potentially implicate the Stark law, [that means that both direct and indirect financial relationships, as well as certain relationships unrelated to DHS, must be analyzed.

Sanctions for violations under Stark will still potentially include, but not be limited to: denial of payment, civil monetary penalties, exclusion from the federal health care programs and potential exposure under the False Claims Act. Given the severity of the sanctions and the expected increase in enforcement efforts, it is imperative that all physicians become familiar with the requirements of the law and adjust their practices accordingly.

The Interim Final Rule may be accessed through the following web link: <http://www.cms.hhs.gov/providerupdate/regs/cms1810ifc.pdf>. If you would like to submit comments regarding the Phase II Interim Final Rule to Cr\15, you should do so as soon as possible in order to increase the likelihood that your comments will be considered (and perhaps publicly addressed) before publication of the Final Rule.

If you have any questions about Stark generally or the Phase II Interim Final Rule and would like our assistance in evaluating your business practices, please feel free to contact our office.