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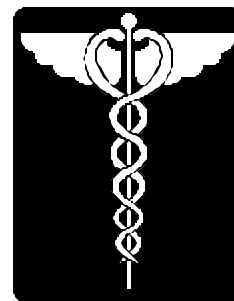


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Message From The Chair

*Bruce C. Stockburger,
Gentry Locke Rakes & Moore, LLP*

It's hard to believe that we are rapidly approaching the end of the 2000-2001 Virginia State Bar year. Several events are scheduled that we hope you will find of interest.

Our traditional May Legislative Update will take on a new look. This year's event will be held on Friday, May 18th and will be a combined effort of the VSB and VBA Health Law Sections. In addition to eliminating a duplicative effort by those who volunteer to make the presentations, several lobbyists will be on the panel to discuss their perspective of the legislative session. The event will take place:

Friday, May 18, 2001

2:30 p.m. to 5:00 p.m.

Virginia Bar Association's Headquarters

B-1 Level Conference Room

7th and Franklin Building

701 East Franklin Street

Richmond, Virginia 23219

As Vice Chairman, Jim Daniel is in the process of organizing our Section's program for the Annual VSB meeting at Virginia Beach on June 15th. The program will be "Ethical Landmines For Health Lawyers" and will address topics that include the attorney-client privilege, internal investigations, U.S. v. Anderson, disclosure of medical records and insurance issues. The program will make use of talent from among our own and we believe will provide much useful information. Please refer to the VSB Summer Meeting Program for time and location at Virginia Beach.

We previously indicated that we were exploring the possibility of sponsoring a full day Health Law CLE program through the VSB CLE organization. This program has become a reality and is scheduled for October 26, 2001 at the Richmond Marriott. It will be a collaborative event with the VBA Health Law Section and Virginia CLE. Although yet to be named, the program is being formatted as six "round table" discussions among colleagues, rather than as straight lectures. Block out the day on your schedules and make plans to attend. We believe you will find the program format refreshing and the topics useful.

As editor of Health Law News, Tom Brown continues to troll for articles that can be distributed through our Section's website. If you have an idea for an article that you believe would be of interest, do our Section a favor and e-mail your ideas to Tom at tbrown@mcguirewoods.com. Better yet, e-mail an article to him!

We look forward to seeing as many of you as possible at the Legislative Update on May 18th and then on to the Summer meeting of the Virginia State Bar in June!



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Final HIPPA Privacy Rule Holds Many Surprises with Many More to Come—How can providers take responsible steps in the face of a moving target?

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Bean, Kinney & Korman, P.C.*

On December 28, 2000, the Final HIPAA Privacy Rule (“Final Rule”) was printed in the Federal Register to take effect on February 26, 2001.¹ The rule itself is just 31 pages long.² However, the preamble and extensive response to the more than 50,000 comments received by the Department of Health and Human Services occupies a daunting 336 pages of the Federal Register.³

The Final Rule is substantially different from the Proposed Rule: in some sections it is more comprehensive and more restrictive, in others it is more permissive. In still others, it is just plain different. The Final Rule covers paper as well as electronic records. It includes restrictions on some employers. It requires patient consent even for treatment, payment and healthcare operations. It opens prior restrictions on marketing and fund-raising. It includes new sub-categories of covered entities and new names for old concepts.

But wait, it gets better: the Rule is likely to change again. This article gives a brief background of the current status of HIPAA Privacy and puts it in the broader perspective of HIPAA Administrative Simplification and finally, it offers some concrete, practical steps to take now, even in the face of a dynamic regulation.

RECENT HIPAA HISTORY

The Final Rule escaped newly elected President Bush’s initial moratorium on new regulations, but was caught in a trickier trap, namely the Congressional Review Act.⁴ Under the Congressional Review Act, Congress must have 60 days to review the impact of any new regulation before it takes effect. In the hectic last days of the Clinton Administration, somehow, the HIPAA Privacy Rule did not make it to Capitol Hill in the proper form. Therefore, the current effective date for the Rule is now April 14, 2001.⁵

In an even more unusual twist, new Secretary of Health and Human Services, Tommy Thompson, opened a 30 day comment period on this already “final” rule.⁶ HHS received a deluge of more than 24,000 additional

comments during the 30 day period. Many sectors of the healthcare industry launched lobbying campaigns to substantially change the Final Rule. However, on April 12, the Administration surprised virtually everyone, and announced that the Final Rule would take effect as scheduled on April 14, 2001.

Even with this “finality”, however, covered entities are hesitant to make a wholehearted effort at compliance. The authorizing legislation permits modifications to the Rule within the first year if it is determined that any parts of it prove unworkable.⁷ The Bush administration has voiced a commitment to putting strong privacy protections into place.⁸ “Our goal is to achieve privacy protection that works. I believe we should be open to the concerns of all those who care strongly about health care and privacy. And after we hear those concerns, our commitment must be to put strong and effective patient privacy protections into effect as quickly as possible.” Statement of Tommy Thompson, U.S. Secretary of Health and Human Services (Feb. 23, 2001) (statement available at www.hhs.gov/news/press/2001pres/20010223.html).

However, in the announcement that the effective date would stay in place, Secretary Thompson indicated that the administration would be taking advantage of the provision permitting changes in the first year.⁹

NOT A BLANK SLATE

Further background is necessary in order to fully understand the regulatory quandary in which health care providers, payors and clearinghouses (“Covered Entities”) now find themselves. It is necessary to take a step back to look at the full context of the various components of HIPAA Administrative Simplification. HIPAA had many components that were meant to permit easier access to health coverage for individuals and that would move the entire healthcare industry toward standardized submissions and transactions through “Administrative Simplification.” The Privacy Rule is just one component of that large plan.¹⁰

In addition to privacy, the Administrative Simplification section also included requirements for the

development of standards for unique identifiers, electronic signatures, transactions, and security. Transaction and Code Set standards were issued in final form in August of 2000.¹¹ The requirement for covered entities to begin submitting covered transactions in these forms takes effect in October of 2002.¹² The Security Standards were issued in a proposed form, but a final rule is not expected until late in 2001.¹³ At this time the neither electronic signature standard nor the Provider, Employer, and individual identifiers have been issued.

Even with all of this uncertainty and these mismatched deadlines, covered entities must still continue to operate and to budget for HIPAA compliance efforts and incorporate HIPAA compliance efforts into their broader long term strategic plans.

STEP BY STEP ACTION PLAN:

1. PUT SOMEONE IN CHARGE

Both the proposed rule and the Final Rule require a designated “Privacy Official.” This person should be identified **now** if they have not already been tapped. Whether this is a full time job or an added duty of an existing position depends on the size and structure of the organization. This person should work closely with whomever is tasked with Security compliance.

In addition, stay flexible: the person chosen today may not be the person who becomes the “Privacy Official” two years from now. In the process of preparing to comply, it may become obvious that the position requires more or less of a person’s time. Even more, it could appear that the position should be at a different level or in a different department within the organization. And finally, it may appear that ongoing compliance requires a different personality or skill set than was needed to get the program moving.

2. PRIVACY OFFICIAL NEEDS TO STAY INFORMED AND EDUCATE OTHERS

The next step is to make sure that the Privacy Official has a working understanding of the new concepts incorporated in the Final Rule and that he or she is monitoring the changes and status of the Rule as they occur. This person should also be sure to identify opportunities for input into changes in the Rule or how it will be implemented. For example, the most recent comment was announced abruptly and was opened for only 30 days. Only those who were watching closely were ready to submit effective, substantive comments.

The person selected must up with the publications and announcements on the rule and the valuable information put out by professional associations.¹⁴ Also, this person should have ongoing contact with the organization’s security officer, legal counsel, and other compliance employees.

3. EVALUATE THE EXISTING POLICIES AND STRUCTURE

Even though there were substantive changes, many concepts are common to both the Proposed Privacy Rule and the Final Rule. These are likely to be seen in the eventual “final” Final Rule. In addition, covered entities are already operating under existing state laws. In order to responsibly address privacy today, each covered entity should undertake an audit of current policies, practices and procedures in at least these areas:

A. Business Partner Agreements/Business Associates Contracts

The name changed from the Proposed to the Final Rule, but the idea is the same.¹⁵ It is vital to identify all outsiders to whom the organization currently disclose health information in the ordinary course of business. This can include billing services, equipment contractors, janitors, document maintenance contractors, IT service vendors, lawyers, accountants, consultants and many more.

Once identified, begin reviewing existing contracts with these entities to see what protections are currently in place to protect patients’ health information once it is in their hands.¹⁶

B. Current Uses and Disclosures

An organization must identify all of the routine uses of health information for payment and healthcare operations. This analysis should focus on whether there are any controls for limiting these uses to the “minimum necessary” information. Who gets what information, and do they really need it?¹⁷

Identify all of the routine disclosures of health information made for purposes other than treatment, payment or healthcare operations. Does the organization use health information for fund-raising? For marketing? For accreditation? Communications with family and loved-ones of

patients? What arrangements have been made to share information for research? What arrangements exist with pharmaceutical companies?

All of these will have to be described in the Notice of Information Practices and may require additional specific authorizations or other hoops to jump through. Fund-raising and marketing are each treated differently in Final Rule as issued in December 2000.¹⁸

C. What Type of Entity is the Organization?

Is it a Hybrid or an Affiliate? A member of an Organized Arrangement? An Indirect Provider or an Employer under the Final Rule? The Final Rule creates categories of covered entities that permit either (i) more limited compliance in the case of Indirect Providers, Hybrid's and Employers or (ii) that permit joint compliance in the case of Affiliates and Organized Arrangements. It is important to identify whether any of these sub-sets may apply to the organization.

D. Access and Amendment

What systems (if any) are in place to respond to patient requests for access to their medical record? To amend their medical record? This provision remains in the Final Rule and is mandated to be in any rule that is ultimately put into effect.

E. Consents and Authorizations

Review consents and authorizations in light of existing state law as well as the Final Rule. Do the existing forms provide consent only for treatment, or for use of the information for treatment and payment? For other purposes? Review the retention policy for consents and authorizations.

The Final Rule creates a continuum of consent for use and disclosures. Unlike the Proposed Rule, it requires a consent for Treatment, Payment and Healthcare Operations.

F. Integration with Existing Policies

Review the employee manual for how it addresses breaches of patient confidentiality.

What sanctions are prescribed? What actions have been taken in the past against employees who breached those policies?

Does the organization have a Fraud and Abuse Compliance Plan? Are they creating one?

4. *RAISE AWARENESS OF PRIVACY AND CONFIDENTIALITY THROUGHOUT THE ORGANIZATION*

Discuss concerns about privacy and potential new requirements with all staff. Conduct interviews of key personnel in various departments to get their perspective.

There may be one Privacy Official, but there are innumerable members of every staff who have access to Protected Health Information. Medical professionals and management have to be involved in and 100% behind this effort. Establishing policies in a vacuum and putting them on a shelf will not produce any benefit for patients or provide any legal protection for the organization.

CONCLUSION

Regardless of any further changes in the final "Final" Privacy Rule, federal regulation of privacy is coming. Even more, public awareness of these issues is being raised and privacy is on patients' minds. Many states, including Virginia, already have private causes of actions for breaches of medical privacy.

Depending on the size and complexity of the organization, it may be possible to do the above audit with existing personnel or it may require help from consultants or outside counsel. One tip, gathering information from individual employees, especially if it is negative, is often more successful if done by an outsider who can assure employees confidentiality.

The time to get to work is now.

¹ Standards for Privacy of Individually Identifiable Health Information; Final Rule 65 Fed. Reg. 82,462 (Dec. 28, 2000) (to be codified at 45 C.F.R. pts.160 and 164); Health Insurance Portability and Accountability Act of 1996, Section F, Pub. L. No. 104-191, 42 U.S.C. § 1320(d) et seq. (hereinafter "HIPAA").

² 65 Fed. Reg. 82,462, 82,798-829 (Dec. 28, 2000).

³ 65 Fed. Reg. 82,462, 82,462-798 (Dec. 28, 2000).

⁴ 5 U.S.C. § 801 et seq. (2000).

⁵ Standards for Privacy of Individually Identifiable Health Information; Final Rule; correction of effective and compliance dates 66 Fed. Reg. 12,433 (Feb. 26, 2001).

⁶ Standards for Privacy of Individually Identifiable Health Information; Final Rule; request for comments 66 Fed. Reg. 12,738 (Feb. 28, 2001).

⁷ Section 1174 of HIPAA in the Administrative Simplification Section gives the Secretary of Health and Human Services the right to make modifications to standards within the first 12 months after the effective date if “necessary in order to permit compliance with the standard.” Codified at 42 U.S.C. § 1320(d)(2)(A). The Final Rule includes the same language. 45 C.F.R. pt. 160.104.

⁸

⁹Statement of Tommy Thompson, U.S. Secretary of Health and Human Services (April 12, 2001) (statement available at www.hhs.gov/news/press/2001pres/20010412.html).

¹⁰⁹. Remember also that privacy could always end up being completely re-legislated by Congress with much broader coverage. There have been Health Privacy bills repeatedly introduced in Congress for more than 10 years, including several in the 105th and 106th Session, after the passage of HIPAA.

¹¹ Health Insurance Reform: Standard for Electronic Transactions; Final Rule 65 Fed. Reg. 50,312 (Aug. 17, 2000) (to be codified at 45 C.F.R. pts. 160 and 162).

¹² 65 Fed. Reg. 50,312 (Aug. 17, 2000) (to be codified at 45 C.F.R. pt. 162.9000).

¹³ Security and Electronic Signatures Standard Proposed Rule 63 Fed. Reg. 43,241 (Aug. 12, 1998).

¹⁴ See list of valuable websites in Appendix A.

¹⁵ 65 Fed. Reg. 82,462, 82,807 (Dec. 28, 2000) (to be codified 45 C.F.R. pt. 164.504(e)(1)).

¹⁶ In this area, it would be best to include consideration of the regulations for Security and the Transaction and Code Sets in the analysis, so efforts are not duplicated. The Security Rule includes a requirement for “Chain of Trust” agreements while the EDI transactions include “Trading Partner Agreements” which all serve related purposes.

¹⁷Use of health information for treatment was exempted from the minimum necessary requirement in the Final Rule.

¹⁸ See requirements for Marketing and Fundraising. 65 Fed. Reg. 82,462, 82,819-20 (Dec. 28, 2000) (to be codified at 45 C.F.R. pt. 164.514(e)-(f)).

APPENDIX A

www.ahima.org/hot.topics/

www.healthlawyer.org

www.healthprivacy.org

www.aspe.hhs.gov/admsimp/index.htm

www.hhs.gov/ocr/hipaa/

www.hipaacomply.com/registration.htm

www.hippo.findlaw.com/hipaa.html

www.mgma.com

www.privacyassociation.org/

www.wedi.org

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This article is meant as a general informational guide and does not purport to be complete or to constitute legal advice.

INSIDE THE MCHIP REGULATORY PROCESS

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The power granted to the states by the Tenth Amendment, known as the police power, is often characterized as among the strongest rights states possess. It includes a state's right to promote the health, safety and welfare of its citizens. While many people recognize a state's right to legislate health laws and promulgate regulations is a constitutionally protected right, few recognize it is likewise a formidable responsibility.

This paper describes the challenges faced and opportunities explored by the Virginia Department of Health ("VDH" or "Department") in its desire to promulgate meaningful regulations for managed care health insurance plans (MCHIPs). It also provides helpful suggestions to regulatory attorneys concerning how best to communicate with and influence regulators while they are in the process of drafting regulations.

NATIONAL MANAGED CARE ISSUES

Managed care is a term that refers to any system of payment or delivery arrangements that controls use of health services by its enrolled members so as to contain costs. Organizations that offer health insurance and medical care at a fixed price are called Health Maintenance Organizations ("HMOs"). Preferred Provider Organizations ("PPOs") are a diverse group of organizations, generally characterized by a network of clinicians, (the preferred providers) that contract to provide service for a discounted fee schedule. Although HMOs were traditionally the most popular type of managed care plan, PPOs now enroll the majority of commercially insured individuals in the United States.

PPOs have a greater number of enrollees, yet they are generally not subject to state regulation concerning quality as are HMOs. There are three reasons often cited for this imbalance. First, PPOs are not typically risk-bearing entities so they may not be subject to state insurance laws. Second, because PPOs often contract with self-insured employers, they may be exempt from state insurance laws pursuant to the Employee

Retirement Income Security Act . Third, some states consider PPOs as a form of fee-for-service insurance because they do not typically interfere with provider practice or treatment decisions.

However, many states are now recognizing that if they are to protect the health and safety of their citizens, they must consider the role of the regulatory process as one tool in ensuring their citizens enrolled in PPOs receive quality care. States that do regulate PPOs generally require accountability in the areas of establishment of grievance and appeals processes and assurances of reasonable access to network providers.

HISTORY OF REGULATIONS CONCERNING MANAGED CARE QUALITY IN VIRGINIA

In 1996, the General Assembly passed Senate Joint Resolution 67 directing the Joint Commission on Health Care and the Bureau of Insurance to study the appropriate role of the agencies of the Commonwealth in overseeing the managed care industry. Rather than define a role, the study described the disagreement among interested parties in deciding the state's role in monitoring managed care. The Bureau of Insurance (BOI) as well as insurance industry and representatives of the business community were reported to support the position that existing regulatory and enforcement activities were appropriate. However, provider groups and patient advocates supported an expanded authoritative role for the BOI. The study noted and applauded the Virginia Department of Health's efforts to formulate a more active role in HMO quality oversight.

In 1997, the General Assembly passed House Bill 2785 directing the State Health Commissioner ("Commissioner") to cooperate with the Bureau of Insurance, the Department of Health Professions, and other state agencies to conduct another study related to managed care. This study was intended to "examine the quality of care mechanisms currently in place for health maintenance organizations ("HMOs") and providers with whom they contract, assess the sufficiency of these mechanisms for ensuring quality . . . , determine the

extent to which such quality of care mechanisms currently exist for forms of managed care other than HMOs (. . .), examine how the Department of Health and the Bureau of Insurance can coordinate their regulatory roles for ensuring quality of health care services in a manner which minimizes overlapping of authority and duplication of resources, and identify the appropriate role of the Department of Health and any other appropriate state agencies in monitoring the quality of care provided through HMOs, other managed care plans, and providers with whom they contract.” Finally, HB 2785 stipulated that the study must “(i) recommend the appropriate role of the Commonwealth in monitoring and improving the quality of care in managed care plans. . . .”

MANAGED CARE STUDY

The study that resulted from HB 2785 was printed as House Document No. 14. It recognized that there were a number of agencies involved with the oversight of quality provided by managed care organizations, but that the oversight was not sufficient. It noted the Code of Virginia did not give the Commissioner authority to promulgate regulations concerning quality of care in HMOs and that absent such statutory authority, the Virginia Department of Health could not establish standards for evaluating such care. The study also pointed out that although the Commissioner was directed by the Code to examine the quality of health care services of any HMO licensed in Virginia, the only quality requirement in the law was one that stated HMOs seeking licensure include a description of their procedures to assess the provision of quality health services.

The study noted that statutes and regulations addressing quality of care in HMOs expressly address particular functions, such as quality assurance plans, complaint procedures and provider networks, but that there was a lack of similar requirements for other managed care organizations performing the same functions. This disparity, the study asserted, created a gap in consumer protection and contributed to a competitive disadvantage for HMOs. The study suggested bringing these other managed care organizations under regulatory oversight where possible. The study concluded by lamenting that both the State Health Commissioner and VDH lack “sufficient statutory authority and regulatory guidance for appropriate oversight of HMO quality.”

The Virginia General Assembly also passed House Joint Resolution (HJR) 611 in 1997. This resolution requested that the State Corporation Commission’s Bureau of Insurance (BOI), in cooperation with VDH, identify the type of health insurance plans that should be considered managed care plans and determine the feasibility of applying statutes and regulations governing HMOs to other forms of managed care health insurance plans. The resultant study, House Document No. 11, proposed the creation of a new chapter in Title 38.2 of the Code that would set forth specific requirements for managed care health insurance plans thereby allowing consistent regulation between all forms of managed health care plans, and encouraging a level playing field in the managed care market.

REGULATORY OVERSIGHT MANDATED

The following year, Governor Gilmore signed Senate Bill (SB) 712 into law. This law presented sweeping changes to the Code and reflected most recommendations presented in House Documents 11 and 14. It mandated meaningful regulatory oversight of managed care health insurance plans by both the BOI and the VDH. It required all MCHIPS so identified by the BOI to secure a certificate of quality assurance from the VDH before their licenses could be attained or renewed. SB 712 authorized the Commissioner of Health in consultation with BOI to impose sanctions for MCHIPs found not to be in compliance with the Code. Finally, it authorized the Board of Health to promulgate regulations governing the quality of care provided to covered persons by MCHIP licensees.

To fulfill its obligation to promulgate regulations, the VDH created an advisory committee. The committee consisted of employees of six MCHIPs nominated by the HMO Association, Health Insurance Association of America and the Virginia Hospital and Health Care Association. There were likewise six persons who were not MCHIP employees but who were either advocates, purchasers or providers. They were nominated or employed by the Patient Advocate Foundation, Virginia Chamber of Commerce, Medical Society of Virginia or the Bureau of Insurance. The VDH hoped this diverse group would voice a broad range of perspectives that VDH would have to consider and address in the drafting of the regulations.

The draft of the proposed regulations was mailed to 300 interested parties. During the comment period twenty-six comments were received. After the Board of Health approved the proposed regulations to go forward

pursuant to the Administrative Process Act, public hearings were held in Fredericksburg, Lynchburg, Richmond, and Newport News. The final regulations were approved by the Board of Health on January 20, 2000.

MCHIP REGULATIONS REOPENED

Within three months of their promulgation, members of the regulated community began to complain that the regulations were difficult to understand and exceeded their statutory authority. Advocates for the PPO community were particularly critical of the regulations believing the regulations assumed most MCHIPs were HMOs and therefore capable of providing information related to the delivery of services. After several meetings with various members of the regulated community, the Commissioner of the Virginia Department of Health, Dr. E. Anne Peterson, decided to reopen the MCHIP regulations in their entirety. On January 29, 2001 the Virginia Regulatory Town Hall posted a notice of the Department's intent to open the MCHIP regulations.

REVISING THE REGULATIONS

The challenge before the VDH in amending the regulations so that they are appropriate to a number of managed care entities is a challenge faced by regulators nationwide. Because HMOs are organizations that offer health insurance and manage medical care, they are likely to have data necessary to measure quality of care. Conversely, PPOs consist of a network of providers who have agreed to accept a discounted payment for PPO patients. The PPO enrollees may receive care from providers within or outside of the network; however, their cost-sharing is lower when they receive care from network providers. Typically, no single provider is held responsible or accountable for delivering comprehensive preventive care or maintaining complete medical records for any PPO enrollee. They often contract with third party administrators to perform administrative functions such as utilization review, physician credentialing, claims processing, etc.

There are also organizational variations within PPOs. Leased PPO networks lease their networks to other PPOs or insurers. Non-risk PPOs contract with employers, insurance companies or third party administrators to provide the payer with network access and potentially other managed care services such as claim repricing, utilization review or quality assurance

activities. Non-risk PPOs are frequently used by self-insured employers, which cover one third of all employees who receive employer-sponsored health benefits. The third type, risk PPOs contract with entities to provide insurance or may do so directly. Although risk PPOs are more likely to have quality data, they are the least popular type of PPO. Thus, PPOs generally do not provide care management services, which is an important fact in measuring quality of care.

In addition to the challenge the VDH faces in drafting regulations that address the differences between HMOs and PPOs, as well as the distinguishing features between PPOs, there are other important considerations. There are myriad interested parties with disparate, yet strong, views regarding what the regulations should and should not require.

LEVEL PLAYING FIELD/QUALITY

Representatives of HMOs want to ensure that the regulations eliminate inconsistencies between all forms of managed health care plans, and encourage a level playing field in the managed care market as stated in House Document 11. PPO representatives want the regulations to have reasonable expectations for all types of PPOs. Consumer groups want the regulations to be rigorous so that the awarding of a certificate of quality assurance to an MCHIP is a guarantee that the MCHIP provides quality services. Purchasers likewise want to be assured the certificate can serve as a litmus test that the MCHIP provides quality services. The VDH must address all of the competing concerns without forsaking its own overriding mission of protecting the health and safety of Virginia citizens.

The VDH has developed a strategy in drafting the regulations aimed at addressing its own concerns and objectives, as well as those of interested parties. First, the regulations will be written with greater specificity. Rather than preface certain sections with language that states "as applicable to the type of MCHIP" to distinguish between types of MCHIPs, the regulations will specify exactly how different types of MCHIPs may satisfy a particular requirement when appropriate. For example, rather than require PPOs to have a quality improvement plan that includes the delineation of expected outcomes for the performance expectations, the Department would accept a quality improvement plan that includes an assessment of covered person and provider satisfaction.

The regulations will likewise recognize inherent

differences between MCHIPs. For example, rather than state all MCHIPs must make available to covered persons procedures for changing primary care providers, the regulations' text will preface the requirement with language reading, "To the extent there are coverage restrictions for changing primary care providers," These changes will provide greater notice to the regulated community of the Department's expectations thereby increasing the potential for voluntary compliance.

Finally, the Department intends to explore making PPOs responsible for quality performance measures in areas in which the PPOs can reasonably be expected to be held accountable. These include access to care, customer service and member satisfaction. The Department believes these areas of accountability are reasonable because they are areas that PPOs typically influence or control.

CONSUMER-FRIENDLY REGULATIONS

The VDH intends to make the regulations more consumer-friendly by requiring MCHIP licensees to provide information concerning their comprehensive onsite examinations in renewal examinations. This information was previously only required of the MCHIP plans. The VDH believes this added requirement enhances the credibility of the quality assurance certificate. In addition to the statutory citation references required by regulatory drafting rules, the VDH intends to refer to statutory citations in sections likely to be of interest to consumers, so as to inform them of the corresponding statutory component. To ensure the regulations do not exceed their statutory authority, the VDH has requested, and intends to continue to request, legal opinions from the Attorney General's office.

Last, but certainly not least, the VDH has broadened the potential for participation by interested parties. The MCHIP Advisory Committee has reconvened and expanded. At each meeting the members review matrices detailing each suggested revision to the regulations, the rationale for the revision if known, the Department's position relative to the suggestion and the Department's rationale for its position. MCHIP Advisory committee members are asked to come to a consensus on all suggested changes. They are then provided with a mark-up of the regulations that reflects the consensus to date.

Information provided to the MCHIP Advisory

Committee is also provided to all interested parties. If the interested party attends the meeting, a hard copy of the materials is made available to him. Or, if he prefers, he can leave his card and the materials will be e-mailed to him. The Department hopes that greater involvement and consensus by a number of parties early in the regulatory process will enable it to draft regulations that will be acceptable to a diverse range of interests.

HELPFUL HINTS FOR REGULATORY ATTORNEYS

This expanded role for interested parties may provide a vehicle by which regulatory attorneys can forward their client's interests. As a former regulatory attorney, I can appreciate some of the obstacles they encounter in communicating with regulators. I have since been employed as an attorney for the Health Care Financing Administration (HCFA) and am now a regulator. I believe I can offer a unique perspective on how best to get the attention of and communicate with regulators.

First, remember that timing is key. Timing is to attorneys what location is to real estate agents. By the very nature of the regulatory process, it is easier to accommodate divergent perspectives early. Be certain to regularly view the regulatory town hall at www.townhall.state.va.us to determine when an agency intends to draft or revise regulations.

Second, while an adversarial approach may be helpful in the courtroom, it serves as an impediment in getting a regulator's attention. In addition, demanding to speak to only high-level officials may serve to delay a response, especially in large agencies such as HCFA. The official will likely forward your question to the appropriate agency employee and in large agencies this may take some time. Such a request may do nothing but serve as an insult to the person best able to answer your question. Fostering an amicable relationship may prove to be helpful when you least expect it.

Third, once the lines of communication are open, be sure to make good use of them. If you are suggesting changes to regulations, prepare a detailed mark-up of them and a document that describes your rationale. This prevents the regulator from having to guess how you would like changes made and why. Any successful effort to sell your suggestion by pointing out how it is consistent with the agency's guiding mission will likely reap a great reward.

Finally, because I am interested in bridging the communication gap that exists between attorneys and

regulators, I invite you to contact me directly should you want to communicate how the MCHIP regulations or the process by which they are being promulgated might be improved. My direct dial number is 804.367.2128 and my email address is rdaniels.vdh.state.va.us.



¹ Kleinman, Lawrence C., M.D., M.P.H., “Conceptual and Technical Issues Regarding the Use of HEDIS and HEDIS-like Measures in Preferred Provider Organizations (PPOs)”, PPO Performance Measurement: Agenda for the Future A National Conference on PPO Quality Issues, Washington, D.C., March 15-16, 2001.

² Hamer, R. and D. Anderson. February 2000. “PPO Operations and Markets”. Available at <http://www.hmodata.com>

³ Carneal G. and G. D’Andrea (Eds.) 1999. The PPO Guide. American Accreditation Healthcare Commission/URAC Washington, D.C.

⁴ Scanlon, Dennis P., “Options for Assessing PPO Quality”. PPO Performance Measurement: Agenda for the Future A National Conference on PPO Quality Issues, Washington, D.C., March 15-16, 2001

⁵ Hamer and Anderson, *supra* at 9.

⁶ See “Study of the Appropriate Role of the Agencies of the Commonwealth in Overseeing the Managed Care Industry Pursuant to SJR 67 of 1996” House Doc. 7 (1997).

⁷ See “The Role of the Commonwealth in Monitoring and Improving the Quality of Care in Managed Care Plans” House Doc. 14 (1998).

⁸ Schauffler, Helen Halpin and Sara McMenamin “Assessing PPO Performance on Prevention and Population Health” PPO Performance Measurement: Agenda for the Future A National Conference on PPO Quality Issues, Washington, D.C., March 15-16, 2001.

⁹ Smith, Dean G. Dennis P. Scanlon “Covered Lives In PPOs”, PPO Performance Measurement: Agenda for the Future A National Conference on PPO Quality Issues, Washington, D.C., March 15-16, 2001.

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¹¹ Hamer and Anderson, *supra*, at 13.

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Must We Use A Professional Corporation or Professional Limited Liability Company For Physician Practices?

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In a recent battle over the enforceability of a non-compete provision in a physician contract, we were confronted with an argument that we thought had been settled in Virginia. Does a physician practice organization wishing to maintain limited liability have to take the form of a professional corporation (PC) or a professional limited liability company (PLC)?

The physician argued that a practice organized in the form of a standard limited liability company (LLC) cannot lawfully engage in the practice of medicine, citing Virginia Code § 54.1-2902 and § 54.1-111. Therefore, the LLC has no legitimate interest to protect by enforcement of the non-

compete provision in a physician contract. Although the case settled before this issue could be addressed by the court, we believe the argument would fail.

I. Virginia has no statutory prohibition against providing professional services through the general LLC form.

Virginia’s original LLC Act stated that LLCs could engage in any lawful business, *except the provision of professional services*.¹ At the time of its enactment, the Virginia LLC Act was the only existing LLC statute that specifically prohibited the use of LLCs by the professional

services industry.² Most other states did not specifically address whether professional service firms could form as LLCs.

In 1992, the General Assembly amended the LLC statute by deleting the prohibition on providing professional services and enacted the Professional Limited Liability Company Act (PLC Act). Instead of requiring professionals to operate in the PLC form, the PLC Act actually has a provision allowing for the voluntary conversion into a standard LLC.³

Our conclusion is that neither the PLC Act nor the LLC Act as the statutes exist today prohibit licensed health care providers from providing professional services through a standard LLC. The fact that a prohibition on professional services was subsequently eliminated from the initial LLC Act supports our position.

II. Virginia has not adopted the corporate practice of medicine doctrine, and physicians are not expressly precluded from being employed by a corporation or an LLC.

The “corporate practice of medical” doctrine is another argument that suggests that physicians may not provide medical services through a standard corporation or LLC. Such an argument is without merit in Virginia.

Courts in other states have developed the “corporate practice of medicine” doctrine, holding that since a corporation may not lawfully practice medicine, a corporation may not employ a physician as an agent to practice medicine for it.⁴ No Virginia court or statute has adopted this doctrine.⁵

As noted in a Virginia Attorney General’s Opinion, Virginia does not adhere to the “corporate practice of medicine” doctrine.⁶ The Attorney General noted that arguments favoring the existence of the doctrine in Virginia are predicated only on inference based on the fact that only an individual, and not a corporation, may be licensed to practice medicine.⁷ The referenced Attorney General’s Opinion concludes that such fact does not preclude a corporation from employing a licensed individual and reasons that if the General Assembly had intended to impose a prohibition on the corporate employment of physicians, it could have done so in some express manner.⁸

Instead of expressly prohibiting the corporate employment of physicians, the General Assembly has enacted several statutes that expressly envision the employment of physicians by entities which are not PCs

or PLCs. We also note that the Virginia Code gives health maintenance organizations the power to furnish health care services through providers (including physicians) that are under contract with or *employed by* the health maintenance organization.⁹ The Virginia Code also provides that no weight loss center or clinic shall, in its name or advertisements, use the words “physicians” or “doctors” or refer to its clients as “patients” or indicate that “medical teams” are available in its facility unless, *inter alia*, the facility *employs or contracts with at least one physician* licensed by the Board of Medicine for services or consultation in connection with the facility’s activities.¹⁰

We further note that no Virginia statute or regulation expressly prohibits a general corporation or limited liability company from engaging in the practice of medicine through its properly licensed employees. To the contrary, the Virginia Medical Malpractice Act defines “health care provider” to include corporations and limited liability companies which *employ or engage a licensed health care provider* and which primarily render health care services.¹¹ This definition was also adopted in the statutes regulating medical care facilities and patient health records privacy, and in worker’s compensation statutes regarding the furnishing of a copy of a medical report.¹² The General Assembly therefore has expressly contemplated the employment of physicians by corporations and limited liability companies with no limitation that such entities be professional corporations or professional limited liability companies.

We further note that prior to 1989, the Medical Malpractice Act required that a “health care provider” be licensed by Virginia.¹³ In 1989, the definition of “health care provider” in § 8.01-581.1 was amended to include professional corporations. A 1994 amendment added corporations and limited liability companies to the definition.

In conclusion, Virginia has never adopted the “corporate practice of medicine” doctrine. Still further, the Virginia legislature has enacted several statutes evidencing its approval of corporate employment of physicians, including employment by general corporations and LLCs.¹⁴

III. An entity cannot be guilty of the unauthorized practice of medicine.

Another rather creative aspect of the argument we recently faced was that a medical practice organized as an LLC was guilty of the unauthorized practice of medicine since it was not organized under the PLC statute. As such, it would be against public policy to allow an entity that was

violating a criminal statute to enforce the covenant not to compete against the former physician employee.

Virginia Code §54.1-2902 states that it shall be unlawful for any person to practice medicine without a valid license issued by the Board of Medicine. Although “person” is not defined by statute, §54.1-2903 does state that a person is regarded as practicing medicine who actually engages in such practice, or who opens an office for such purpose, or who advertises or announces to the public in any manner a readiness to practice or who uses in connection with his name the words or letters Doctor, Dr., M.D., D.O., D.P.M., D.C., Healer, or any other title, word, letter or designation intending to designate or imply that he is a practitioner of the healing arts or that he is able to heal, cure or relieve those suffering from any injury, deformity or disease. The statute also lists the following acts considered *prima facie* evidence that one is practicing the healing arts: signing a birth or death certificate, signing any statement certifying that the person signing has rendered professional service to the sick or injured, or signing or issuing a prescription for drugs or other remedial agents. The clear implication is that only a natural person can be guilty of the unauthorized practice of medicine, since only a living person can perform any of the enumerated acts.

Unlike the unlawful practice of medicine provision, the unlawful practice of architecture and engineering provision, in Virginia Code § 54.1-111, by virtue of § 54.1-406, expressly applies to any person, partnership, *corporation or other entity* offering to practice architecture, engineering, or land surveying without being properly registered or licensed. [*Emphasis added*]. No such language appears in the unlawful practice of medicine statute. As both unlawful practice provisions appear in Title 54.1 of the Code of Virginia, had the legislature considered that an entity could be considered to be engaging in the unlawful practice of medicine, it would have included an express provision in the unlawful practice of medicine provision.

As further support for our position, the requirements for licensure in Virginia’s regulations governing the practice of medicine plainly apply to natural persons, not entities, because only natural persons can meet licensing requirements, i.e., educational requirements.¹⁵ No Virginia statute or regulation sets forth a procedure for a corporation, professional corporation, limited liability company, or professional limited liability company to hold a license to practice medicine. See 18 VAC 85-20-10 et seq.; Chapters 24 and 29 of Title 54.1 of the Code of Virginia. (This was confirmed to us by Ms. Ola Powers, Deputy Executive Director, Licensing, of the Virginia Board of Medicine in her letter of January 8, 2001).

Our conclusion is that Virginia’s unauthorized practice statute does not encompass entities, nor does it preclude a physician practice from organizing a standard corporation or LLC. The statute describes unauthorized practice as activities in which only a natural person could engage. Unlike the unauthorized practice of architecture or engineering statute, the unauthorized practice of medicine statute does not expressly apply to entities, such as corporations or LLCs. Further, as Virginia’s Board of Medicine has acknowledged, Virginia has no procedures by which an entity, professional corporation or otherwise, could even obtain a license to practice medicine. The purpose of the unauthorized practice of medicine provision is to protect the public. The public is not at risk of danger from an LLC practicing medicine because an LLC can only practice medicine through its properly licensed employees. Therefore, an LLC which practices medicine through its licensed physician employees cannot violate the unauthorized practice of medicine statute.

IV. Physician Practices May Organize as Standard Corporations or LLCs.

Although the arguments made by the former physician employee attempting to repel enforcement of a covenant not to compete were very creative, we believe they would fail judicial scrutiny. We conclude that physician practices may organize as a standard corporation or LLC, and are not restricted to using professional corporations or PLCs. Use of the standard corporation or LLC may provide the flexibility to modern medical practices that is required to remain competitive in the ever-changing health care arena.



¹ Virginia Code § 13.1-1008 (Michies 1991).

² See Connaughton, *The Dawn of the Limited Liability Company in Virginia: An Analysis of the Statute*, 14 Geo. Mason U. L. Rev. 177, 197 (1991).

The statement of a Virginia legislator expressed the reason why the Virginia legislature imposed the original prohibition in the regular LLC Act: “Generally, in Virginia we did not want the legislators to perceive the LLC Act as special interest legislation. We had not received any actual objections – there were just the informal discussions among our drafting committee to the effect that if lawyers and accountants are perceived to be the beneficiaries of this legislation it may be more difficult to get it enacted.” *Id.* quoting comments of James J. Wheaton at the Meeting of the Ad Hoc Subcommittee on Limited Liability Companies, Committee on Partnerships and Unincorporated Business Organizations, Section of Business Law, American Bar Association (Nov. 1991).

³ Section 13.1-1117 of the PLC Act provides, in part, that by a 2/3 vote of the members, the PLC shall be treated as converted into a general LLC.

⁴ 1992 Op. Atty. Gen. Va. 147.

⁵ *Id.*

⁶ *Id.*, n.1.

⁷ *Id.*

⁸ *Id.*, citing Va. Code §§ 54.1-2901, 54.1-2902.

⁹ § 38.2-4303(3).

¹⁰ §18.2-502.1.

¹¹ Va. Code § 8.01-581.1, *et seq.*

¹² § 32.1-127.1:03, § 65.2-604

¹³ See Turner v. Sheldon D. Wexler, D.P.M., P.C., 244 Va. 124, 418 S.E.2d 886 (1992).

¹⁴ See footnote 12 above.

¹⁵ See 18 Vac. 85-20-120.

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Ninth Circuit Hands IRS Major Win In Taxation of Non-Profit/For-Profit Joint Ventures

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The U.S. Court of Appeals for the Ninth Circuit has handed the Internal Revenue Service a significant win in the *Redlands Surgical Services v. Commissioner* case (9th Cir., No. 99-71253, 3/15/01). The Ninth Circuit rubber-stamped the U.S. Tax Court's 1999 decision that a hospital-subsidiary partner in a health care joint venture is not tax-exempt. *Redlands Surgical Services v. Commissioner*, 113 T.C. 47 (1999). The U.S. Tax Court's decision in *Redlands* upheld the IRS's 1997 denial of tax-exempt status to Redlands Surgical Services ("RSS"), a California non-profit public benefit corporation. That decision also upheld the IRS's rationale in Revenue Ruling 98-15, which provides guidance on whole hospital joint ventures between tax-exempt hospitals and for-profit hospitals. Rev. Rul. 98-15, 1998-1 C.B. 718.

Background to Redlands Case

The facts in the case are somewhat complicated. A tax-exempt health care system created RSS to be a 46 percent partner in a general partnership ("General Partnership") with a for-profit entity that would be the other 54 percent general partner. The new General Partnership would then be the general partner in a

limited partnership that would operate an ambulatory surgical center. RSS had no employees. Its only activity was (and continues to be) its involvement in the General Partnership.

RSS sought tax-exempt status on the basis of its involvement in the General Partnership. The IRS denied tax-exempt status, stating that RSS is not operated exclusively for charitable purposes because it operates for the benefit of private parties and fails to benefit a broad cross-section of the community. In holding for the IRS, the Tax Court looked at the following factors (no one factor alone was determinative): (1) there was a lack of any express or implied obligation for the for-profit interests involved in RSS' sole activity to put charitable objectives ahead of noncharitable objectives; (2) RSS' lack of voting control over the General Partnership (voting was split 50/50 with an arbitration provision); (3) RSS' lack of formal or informal control sufficient to ensure furtherance of charitable purposes; (4) a long-term management contract giving the for-profits interests control over day-to-day operations as well as a profit-maximization incentive; and (5) the market advantages and competitive benefits secured by the for-profit interests as a result of the arrangement.

Ninth Circuit's Decision

The Ninth Circuit's *per curiam* decision embraces the Tax Court's opinion and implicitly upholds Revenue Ruling 98-15. The *per curiam* decision follows:

We deny the petition for review on the grounds stated by the tax court in *Redlands Surgical Servs. V. C.I.R.*, 113 T.C. 47 (1999). Specifically, we adopted the tax court's holding that appellant Redlands Surgical Services "has ceded effective control over the operations of the partnerships and the surgery center to private parties, conferring impermissible private benefit. [Redlands Surgical Services] is therefore not operated exclusively for exempt purposes within the meaning of sec. 501(c)(3), I.R.C. 1986." *Id.* 47. We also affirm the tax court's conclusion that the benefit conferred on private parties by the surgery center's operations prevents Redlands Surgical Services from attaining tax exempt status under the integral part doctrine.

Although the Ninth Circuit's opinion demonstrates the court's willingness to adopt the IRS's analysis with respect to joint ventures between non-profit and for-profit entities, it provides no guidance to assist taxpayers in analyzing such joint ventures to determine the effect on the non-profit's tax-exempt status. Revenue Ruling 98-15 analyzes joint ventures by providing two examples — one good and one bad. The examples are at the extremes, whereas most joint ventures fall somewhere between the two. A well reasoned opinion from the Ninth Circuit would have greatly assisted taxpayers. Notwithstanding the lack of guidance in the decision, the Ninth Circuit's opinion will clearly be viewed by the IRS as upholding the analysis it has been applying for years and likely cause the IRS to move forward with challenging many joint ventures.

The *Redlands* decision goes well beyond joint ventures in the health care industry. It affects all joint ventures between non-profit and for-profit entities. Probably the most significant aspect about the *Redlands* decision is that it apparently endorses the IRS's position that the non-profit organization must be in control of the joint venture if the organization is going to retain (or obtain) tax-exempt status. Although for-profit entities may be willing to share control with a non-profit organization, they are less likely to participate in a joint ven-

ture if the non-profit organization must be in control. In fact, there are many shared-control joint ventures that are now going to have to take a careful look at their structure.

To better understand the *Redlands* decision, one needs to consider the background for Revenue Ruling 98-15.

Background to Revenue Ruling 98-15

The IRS historically argued that a non-profit, tax-exempt entity that is described in Section 501(c)(3) of the Internal Revenue Code could not participate in a joint venture as a general partner with a for-profit entity without violating the Section 501(c)(3) requirements. (Non-profit hospitals generally meet the requirements of Section 501(c)(3) and are referred to as Section 501(c)(3) organizations.) Its reasoning was that the non-profit's fiduciary obligations as a general partner to promote the interests of the for-profit partners of the joint venture were *per se* incompatible with the requirements that the non-profit operate exclusively for tax-exempt purposes. After losing the *Plumbstead Theatre Society v. Commissioner* case in the U.S. Court of Appeals for the Ninth Circuit in 1982, the IRS modified its position. It developed the following informal two-step analysis to determine whether a non-profit entity would retain its tax-exempt status if it participates in a joint venture with a for-profit entity:

1. Does the participation by the non-profit entity in the joint venture further its tax-exempt purpose?
2. Does the arrangement allow the non-profit entity to act exclusively in furtherance of its tax-exempt purposes and not for the benefit of the for-profit partners?

Non-profit hospitals forming joint ventures with for-profit hospitals have had difficulty applying the two step analysis. The factors the IRS considers in determining whether the requirements of the analysis are met have not been clear. Moreover, it had not been certain whether the IRS would follow its informal policy. Accordingly, non-profit hospitals requested guidance from the IRS.

The IRS response

The IRS responded to requests for guidance by issuing Revenue Ruling 98-15. In typical IRS fashion,

the revenue ruling sets forth two extreme factual situations involving the creation of a joint venture to operate an acute care hospital. In Situation 1, participation in the joint venture does not violate the Section 501(c)(3) requirements (*i.e.*, the requirements for tax-exempt status). In Situation 2, participation in the joint venture does violate the Section 501(c)(3) requirements.

Some factors are common to both situations. The common factors are:

1. *Non-profit forms joint venture with for-profit.* A non-profit corporation that owns and operates an acute care hospital and meets the requirements of Section 501(c)(3) (the “NPH”) forms a limited liability company (“LLC”) with a for-profit corporation that owns and operates a number of hospitals (the “FPH”);
2. *Both entities contribute assets.* The NPH contributes all its operating assets (which include the hospital facility) to the LLC, and the FPH contributes assets to the LLC;
3. *Proportionate interests.* The NPH and FPH each receives an interest in the LLC proportional and equal in value to their respective contributions; and
4. *Non-profit uses proceeds to fund exempt activities.* The NPH intends to use any distributions it receives from the LLC to fund grants to support activities that promote the health of the NPH’s community and to help the indigent obtain health care. The NPH’s grant making activities, which will be funded substantially by distributions from the LLC, and its participation as an owner of the LLC will constitute its only activities.

Factors That Cause Different Results

Situation 1 has “good” factors, which cause the favorable result, while Situation 2 has “bad” factors, which cause the unfavorable result. The good factors in Situation 1 are:

1. *Non-profit controls joint venture.* The governing board that will manage the LLC (the joint venture) consists of three individuals chosen by NPH and two individuals chosen by FPH (*i.e.*, the NPH controls the LLC).
2. *Joint venture’s documents require charitable purpose.* The LLC’s governing documents require

that the LLC operate any hospital it owns in a manner that furthers charitable purposes by promoting health for a broad cross section of the community, and that this overrides any duty the LLC may have to operate for the financial benefit of its owner.

3. *Independent community leaders on board.* The NPH will appoint to the governing board community leaders who have experience with hospital matters, but who are not on the hospital staff and do not otherwise engage in business with the hospital.
4. *Amendments require joint approval.* The NPH and FPH must both approve any amendment to the LLC’s governing documents.
5. *Major amendments require board approval.* A majority of three board members must agree to certain major decisions relating to the LLC’s operations (*e.g.*, capital and operating budgets, distributions of earnings, selection of key executives, acquisitions or dispositions of health care facilities, large contracts, services offered, and renewal or termination of management agreements.)
6. *Independent management company.* The LLC enters into a management agreement with a management company that is unrelated to either the NPH or FPH to provide day-to-day management services to the LLC. The management agreement is for a five-year period, is renewable for an additional five-year period by mutual agreement, and can be terminated by the LLC for cause. The management company will be paid a fee for services that is based on the LLC’s gross revenues. (The fee, as well as all other terms and conditions, are reasonable).
7. *Decision makers forming joint venture not promised employment, etc.* None of the officers, directors, or key employees of the NPH who were involved in making the decision to form the LLC were promised employment or any other inducement by the LLC or the FPH and their related entities if the transaction were approved. Nor do any of these individuals have any interest, directly or indirectly, in the FPH.

Bad Factors in Situation 2

Although some of the factors in Situation 2 are similar to those in Situation 1, the “bad” factors in Situation 2 are:

1. *Non-profit does not control joint venture.* The governing board of the LLC consists of three individuals chosen by the NPH and three individuals chosen by the FPH (*i.e.*, the NPH does not control the LLC.)
2. *Joint venture documents do not require charitable purpose.* The LLC’s governing documents do not require that the LLC operate any hospital it owns in a manner that furthers charitable purposes by promoting health for a broad cross section of the community.
3. *Board approval not required for certain significant acts.* Approval of a majority of the board members is not required for (i) all distributions of the LLC’s earnings, but only for distributions over a certain minimum level, (ii) the acquisition or disposition of health care facilities, although a majority of board members is required for unusually large contracts, or (iii) renewal or termination of management agreements.
4. *For-profit controls management company.* The LLC enters into a management agreement with a wholly-owned subsidiary of the FPH to provide day-to-day management services to the LLC. The management agreement is for a five-year period, and is renewable for an additional five-year period at the discretion of the FPH’s subsidiary.
5. *Former employees of for-profit employed by joint venture.* The NPH agreed to approve the selection of former employees of the FPH to serve as the LLC’s chief executive officer and chief financial officer.

The Good and the Bad - the IRS Perspective

In holding that the NPH in Situation 1 will continue to meet the Section 501(c)(3) requirements when it participates in the LLC, the IRS focuses on the NPH’s ability to control the LLC, the LLC’s commitment in its governing documents to exempt purposes, and the flow of information on the LLC’s activities (*e.g.*, the hospital’s activities). It contrasts these factors with those

in Situation 2, and holds that the NPH in Situation 2 violates the Section 501(c)(3) requirements.

Non-profit’s control v. shared control. In Situation 1, the NPH, through its appointment of a majority of the governing board and the specifically enumerated powers of the board over changes in activities, can ensure that the assets it owns through the LLC and the activities it conducts through the LLC are used primarily to further exempt purposes. Such control also enables the NPH to ensure that the benefit to the FPH and other private parties, like the management company, will be incidental to the accomplishment of its charitable activities. In Situation 2, the NPH does not control the governing board of the LLC, and therefore, is not able to initiate programs within the LLC to serve new health needs of the community without the agreement of at least one governing board member appointed by FPH. The ability to block programs initiated by the FPH board members that do not promote exempt purposes is not enough. The NPH board members must have the power to initiate their exempt purpose programs.

Charitable purpose requirement v. no requirement. The governing documents of the LLC in Situation 1 commit the LLC to providing health care services for the benefit of the community as a whole and to give charitable purposes priority over maximizing profits for the LLC’s owners. This binding obligation precludes the LLC from denying care to segments of the community, such as indigents. No such binding obligation exists in Situation 2. Thus, in Situation 2, the LLC will not necessarily give priority to the health needs of the community over the consequences of the LLC’s profits.

Independent management company v. controlled management company. In both Situations 1 and 2, the fee to be paid to the management company is reasonable. In Situation 2, however, the management company will have broad discretion over the LLC’s activities and assets that may not always be under the board’s supervision. For example, the management company is permitted to enter into all but “unusually large” contracts without board approval. Moreover, the management company, which is a subsidiary of FPH, may unilaterally renew the management contract.

Independent source of information v. controlled source. In both Situations 1 and 2, the primary source of information for the NPH board members will be the chief executives of the LLC and the management company. In Situation 1, the management company is unrelated to NPH and FPH, and it appears that the chief

executives of the LLC are also unrelated to NPH and FPH. Thus, the NPH board members will receive their information on the hospital's activities from independent third parties. This is not the case in Situation 2. There, the management company is a subsidiary of the FPH, and the chief executives of the LLC are previous employees of the FPH.

Revenue Ruling 98-15 after Redlands

With the *Redlands* decision's implicit acceptance of Revenue Ruling 98-15, adherence to the factors in Situation 1 is going to become more important. In many, if not most, of the joint ventures that have been formed, the non-profit hospital shares control of, but does not control, the governing body of the joint venture entity (e.g., 50/50 control of the LLC). This lack of control now appears to be fatal.

What about the governing provisions of the joint venture? Must they provide that the joint venture operate activities of the joint venture in a manner that furthers charitable purposes of the non-profit organization and that this responsibility override any duty to operate for the financial benefits of the joint venture owners? Probably yes. Without such provisions, the IRS will likely contend that the non-profit organization is not operating exclusively for exempt purposes.

A major accounting firm recently announced that the IRS had issued a favorable determination letter to a non-

profit health care organization that formed a joint venture with a for-profit entity. It appears from the announcement and other reports that the factors in the case are very similar to the good factors in Situation 1 of Revenue Ruling 98-15. The non-profit health care organization controls the joint venture, and the IRS required the governing documents to be amended to ensure that charitable purposes would take priority over making profits. The only significant difference from the good factors in Situation 1 is that the for-profit minority partner manages the day-to-day activities of the joint venture. Given the similarity to the good factors in Situation 1, it is debatable whether the determination letter indicates a "softening" of the position in Revenue Ruling 98-15.

The continuing challenge for non-profit and for-profit hospitals and their advisors after the *Redlands* decision is to determine which mixtures of good and bad factors (if any) will preserve the non-profit organization's tax-exempt status and which mixtures will result in a loss of tax-exempt status.



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GENERAL ASSEMBLY LEGISLATIVE UPDATE

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Of the nearly 2700 bills and resolutions introduced in the General Assembly in the 2001 session, approximately 260 of them were health-related in nature. In an attempt to meet Virginians' concerns regarding the Commonwealth's role in health care, the newly enacted legislation covers a wide gamut from studying treatment options for criminal offenders with mental illness and substance abuse disorders to a prohibition against human cloning. Of the 260 proposed pieces of health legislation introduced in either the House or the Senate, the following is a discussion of some of the more significant and/or interesting pieces of legislation:

- 1. Deregulation of COPN Services** House Bill 2155, Senate Bill 1084, **FAILED**

Without a doubt, the most important health care related issue debated in this most recent legislative session involved the deregulation of the certificate of public need (COPN) laws in Virginia.

Both bills regarding the regulation of health care facilities introduced in both the House and Senate failed. The legislation would have established a three-phase plan for deregulation of the requirements of COPN services as was required under Va. Code §32.1-102.13. Va. Code §32.1-102.13 required the Joint Commission on Health Care (JCHC), after collaborating with an number of organizations, to formulate a deregulation plan for the General Assembly to consider in the 2001 session.

The bills introduced on the COPN adopted a majority of the proposals set forth in the JCHC deregulation plan. Under the legislation, the three phases of deregulation would phase out specific types of equipment and services from the requirements of the COPN. The Virginia Board of Health would instead regulate such services through licensure requirements to ensure that each of the services maintained compliance with any relevant national accreditation standards. Phase I would deregulate services such as computed tomographic (CT) scanning, lithotripsy, magnetic source imaging (MRI), positron emission tomographic (PET) scanning and all nuclear medicine imaging. Phase II would permit the introduction of cardiac catheterization, gamma knife surgery and radiation therapy services without a COPN. Phase III would remove ambulatory surgery centers, neonatal special care, obstetric services, open-heart surgery and organ transplantation services from the list of services that require a COPN.

Proponents of deregulation maintain that phasing out the COPN requirements over an extended period of time would serve a number of purposes including expansion of the market and quality of services that patients can obtain as well as the promotion and improvement of access to health care for those Virginians who could not access such services as readily under the COPN requirements, namely the indigent and uninsured. All COPN legislation was tabled because the General Assembly was not able to come up with the necessary funding for implementation of the legislation. Proponents of the COPN deregulation legislation were adamant that the legislation would be implemented in one complete package that included funding. A piecemeal implementation would have, according to the proponents, thwarted the original purpose and importance of the legislation. Consequently, without funding, the legislation was tabled. However, it will be the focal point of the health care legislative efforts in the 2002 legislative session.

2. Request for review by medical malpractice review panel, Senate Bill 907, PASSED

Senate Bill 907 amends and reenacts Va. Code §8.01-581.2 to permit the circuit court judge to set the trial date in a medical malpractice case after the case has been referred to a medical malpractice review panel. Prior to the passage of Senate Bill 907, once the case was referred to a medical malpractice review panel, a trial court judge was

prohibited from setting a trial date for such case, even though the judge was permitted to rule on any motions, demurrers, or pleas that could be ruled on as a matter of law. This legislation responds to the discrepancies in outcomes on the trial court level with respect to setting a trial date. Some judges have interpreted the statute, prior to amendment, to prohibit them from setting a trial date, while others have set trial dates without issue.

3. Informed Consent for Abortion, House Bill 2570, Senate Bill 1211 PASSED

House Bill 2570 and Senate Bill 1211 (identical bills) establish specific procedures that physicians performing abortions must follow to obtain the informed written consent of a pregnant woman prior to performing an abortion. The legislation amends and reenacts Va. Code §§16.1-77 and 18.2-76 as such sections relate to abortion and informed written consent as a prerequisite for a lawful abortion and the penalties imposed for lack of adherence to the requirements set forth in obtainment of a written informed consent. Information provided to the pregnant woman prior to obtaining the consent must be provided at least 24 hours prior to the abortion by the physician who will perform the abortion, the referring physician, or a licensed professional or practical nurse who work directly under either the physician who will perform the abortion or the referring physician. Such information must include explanations of the following concepts and ideas to the pregnant woman:

- a) The procedures to be performed and any associated risks and benefits of such procedures as well as alternatives to the procedure;
- b) That the pregnant woman may withdrawal her consent at any time before undergoing the procedure;
- c) That the physician who will perform the abortion is available to the pregnant woman should she have any questions or concerns regarding the procedure;
- d) The gestational age of the fetus at the time the procedure is to be performed;
- e) The availability of printed materials created by the Department of Health and an additional allowance of time for the pregnant woman to read the materials prior to giving her consent.
- f) In addition to instructing the woman on the availability of such Department of Health printed materials, the physician's offer of materials also

must include advice that the printed materials contain the information on:

- i) available alternatives to abortion;
- ii) availability of medical assistance benefits for prenatal care, childbirth and neonatal care;
- iii) the legal responsibilities of the biological father for support, the availability of services to assist the pregnant woman in collecting support should she decide to continue her pregnancy; and
- iv) the pregnant woman's right to review the Department of Health materials free of any charge to her.

The revised and amended statute also requires the creation of such materials by the Department of Health by an October 1, 2001 deadline. The statute also details explicit information that the Department of Health must include in the printed materials.

4. Study of Treatment Options for Offenders with Mental Illness or Substance Abuse Disorders, Senate Bill 440, PASSED

Pursuant to Senate Bill 440, the Joint Commission on Behavioral Health Care, the Virginia State Crime Commission and the Virginia Commission on Youth will conduct a study of potential treatment options for criminal offenders who have been diagnosed with mental illness or substance abuse disorders. Treatment of mental illness and substance abuse disorders would, according to Senate Bill 440, reduce disciplinary problems and recidivism, improve the offender's chance of success upon release, and reduce costs for the taxpayers of Virginia. The study will consider the incidence of mental illness and substance abuse among criminal offenders; the current system for providing mental health and substance abuse services; model treatment programs for offenders; a cost benefit analysis of public treatment services; the need for specialized law enforcement training to identify and handle offenders with mental illness or substance abuse disorders; and the level of funding necessary for such assessment and treatment services that would be necessary.

5. Human Cloning, House Bill 2463, Senate Bill 1305, PASSED

Va. Code §§32.1-162.21 and 32.1-162.22, added to the Virginia Code as a result of House Bill 2463 and Senate Bill 1305, strictly prohibit human

cloning, implanting or attempting to implant the product of a somatic cell nuclear transfer into a uterus in order to initiate a pregnancy, possessing any product of human cloning or shipping or receiving a somatic cell nucleus transfer in commerce for the purpose of cloning. Any person who violates the human cloning statute faces civil penalties in the amount of \$30,000 for a violation.

6. Breast Cancer Underwriting and Preexisting Condition Restrictions, House Bill 2063, PASSED

The addition of Va. Code §38.2-3407.11:3 prevents insurers, corporations who administer their own health insurance subscription plans and health maintenance organizations from basing decisions regarding denial of coverage on the fact that a person has a high risk of breast cancer or has had breast cancer in the past, but has been cancer-free for at least five years. Under the new Va. Code §38.2-3407.11:3, people with a high risk of breast cancer or those who have had breast cancer in the past (but not within the past five years) are protected from adverse decisions based specifically on their status and are provided with the same benefits as provided for persons with a general physical illness as opposed to those benefits offered to a high risk patient.

7. Medical Malpractice Definition of Health Care Provider, House Bill 1773, PASSED

House Bill 1773 expands the definition of "health care provider" to include directors, officers, employees and agents of those persons or entities defined as health care providers acting within the scope of their employment. Medical malpractice liability will now extend to reach those persons such as directors and officers who were once protected by the limited liability of their choice of entity.

8. OB/GYN Referral to Specialist, House Bill 1800, PASSED

This legislation prohibits insurance carriers from requiring patients to have an office visit with their primary care physicians prior to getting a referral to a specialist from the patient's obstetrician-gynecologist. Depending on the circumstances involved, the primary care physician will still play a role in the patient's referral to a specialist, but the patient is not required to have an office visit with the primary care physician in order to fulfill the primary care physician's role in the referral.

9. Prescription Benefit Cards, House Bill 2654, PASSED

House Bill 2654 amends and reenacts Va. Code §2.1-20.1 and 32.1-325 to require all health insurers, corporations that self insure and health maintenance organizations (HMOs) that provide outpatient prescription drug coverage to provide prescription drug cards, health insurance benefit cards or any other recommended related technology to each person covered under the plan or policy. The information on the prescription benefit card must include the covered person's name and identification number, telephone number that providers may call to request pharmacy benefit assistance and electronic transaction routing information as well as other numbers required by the insurer, corporation, HMO or benefit administrator to electronically process a prescription claim.

10. Outpatient Data Collection, House Bill 2763, PASSED

The Va. Code §§32.1-276.3, 32.1-276.6, 32.1-278 and 32.1-276.9 requirements for reporting outpatient surgery procedures to the Virginia Patient Level Data System by an inpatient hospital are extended by House Bill 2763, to include general, ordinary and outpatient surgical hospitals, facilities licensed or certified pursuant Va. Code §32.1-123 et seq., and every physician performing surgical procedures in his/her office. The legislation contemplates that the Virginia Patient Level Data System, a non-profit organization, will conduct a pilot program to determine the logistical, fiscal impact of such required reporting in addition to the usefulness of such a reporting program to determine its overall impact.

11. Health Care Record Copying Charge, House Bill 2864, PASSED

House Bill 2864 amends Va. Code §8.01-413 to expand the cost limits for health care provider's charges for copies from exclusively including paper records (fifty cents for each page up to fifty pages and twenty-five cents per page thereafter) to including any hard copy generated from computerized or other electronic storage, other photographic, mechanical, electronic, imaging or chemical storage process.

12. Medical Malpractice Cap, Senate Bill 808, PASSED

Between 1999 and 2001, some plaintiffs attempted to argue that there was no malpractice cap for actions occurring prior to August 1, 1999. The plaintiffs' arguments focused on the fact that the time period prior to August 1, 1999 was not mentioned in the statute as it was amended by the 1999 General Assembly to increase the cap for actions occurring after August 1, 1999. In order to clarify the intent of the amendment, Senate Bill 808 amends Va. Code §8.01-581.15 to include language that the cap for any malpractice that occurred prior to August 1, 1999 will be the amount set forth in the statute at the time the act of malpractice occurred.

13. Requirements for Notification of Adverse Decisions, Senate Bill 955, PASSED

In an effort to create more accountability of health insurance carriers, this legislation requires that if a utilization review entity makes an adverse decision regarding the treatment requested for a patient, the treating physician must be provided with the name, address and telephone number of the person who made the adverse decision. Senate Bill 955 amends §32.1-137.13, which only required the entity to provide the treating physician with a contact in the organization.

14. Access to Physical Therapy, Senate Bill 1367, PASSED

Senate Bill 1367 enables patients to have limited direct access to their physical therapists provided that the relationship originated upon the referral of the patient to the physical therapist by the patient's physician, (M.D. or D.O.), chiropractor, podiatrist within a two-year period prior to the direct access. Senate Bill 1367 requires that the physical therapists have either practiced upon the referral of or at the direction of a licensed physician, chiropractor or podiatrist for at least three years prior to seeing the patient directly. Also, the maximum amount of direct access treatment without a referral is limited to fourteen days, the physical therapy must be provided for the same injury, disease or condition for which the patient was originally referred and the physical therapist must notify the patient's practitioner within three days of beginning the physical therapy.

15. Practice of Dentistry, Senate Bill 806, PASSED

The structure and definition of the practice of dentistry as it was set forth in Va. Code §§54.1-2700

and 54.1-2709.4 is modified by Senate Bill 806. As amended, Va. Code §54.1-2700 defines dentistry as “evaluation, diagnosis, prevention, and treatment, through surgical, nonsurgical or related procedures, of diseases disorders, and conditions of the oral cavity and the maxillofacial, adjacent and associated structures and their impact on the human body.” The amended statutory language expands the definition to include oral and maxillofacial surgeons who perform dental procedures as providers who are subject to the dentistry rules and regulations. These oral and maxillofacial surgeons who perform dental procedure are also required to obtain certification from the Board of Dentistry in order to perform dental procedures. In addition, the legislation establishes guidelines for the form and severity of discipline that the Board of Dentistry should impose on dentists or dental hygienists that practice beyond the scope of their licenses. This legislation enables the statutory law on dentistry to adjust and adapt to the growing popularity of cosmetic dentistry and to prevent unqualified providers from performing procedures that they are not qualified to perform.

Aside from the legislation discussed above that passed, in addition to the COPN legislation, there were a number of health-related bills that failed for one reason on another. While these pieces of legislation failed, they are still important to recognize because they reflect the greater realm of current health care issues under debate. Among those bills that fit into this category are the following:

1. HMO Liability for Health Care Treatment Decisions, House Bill 2350, FAILED

House Bill 2350 would have established a cause of action against health maintenance organizations (HMO) for failure to provide those persons covered by the HMOs with ordinary care in making health care decisions on behalf of such persons. The legislation permitted private persons to directly file the cause of action with the court without first exhausting the utilization review process set forth by the HMO.

2. Medical Malpractice Review Panels, Privileged Communications, House Bill 2500, FAILED.

This legislation provided that any person who is the subject of the proceedings, minutes, records or reports of any medical staff committee, utilization review committee or other medical malpractice review committee would be permitted to receive a

copy of any document produced or utilized that concerned the person.

The 2001 General Assembly session brought very little significant change to health care laws in the Commonwealth. While there were a number of bills passed, none truly change the landscape of health care in Virginia. As for next year’s battlegrounds, COPN deregulation will most likely continue to be at the top of the list. While the JCHC no longer has a mandate from the General Assembly to study the COPN, it, along with the other interested parties, will likely continue to do so in an effort to further the legislation that was tabled this year.

In addition to the COPN legislation, other hot health care topics for the 2002 General Assembly may include the following: (i) a proposal for the establishment of a coalition to study health care staffing levels, particularly concerning the scarcity of available nurses, (ii) the reformation of state tax exemption laws for non-profit organizations (legislation proposed this year, which forced not-for-profit organization to pay state sales tax and then apply for a rebate of that money may resurface in the 2002 session) and (iii) new legislation reflecting the current national trend toward making managed care organizations (MCOs) and insurance companies more accountable to providers and patients which will require changes to the Fair Business Practices Act (e.g. eliminating profiling as the sole basis of seeking overpayments and expanding the definition of retroactive denial to include all attempts by the insurance companies and MCOs to recover overpayments).

As always, the Virginia Bar Association continues to play a vital role in the legislative process. Members of the Health Law Section are encouraged to express their views and opinions on health care legislation pending before the General Assembly.



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