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Message from the Chair

Thomas C. Brown, Jr., McGuireWoods LLP

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The Health Law Section ends its 2002-2003 bar year with a number of accomplishments to its credit.

The Section successfully moved its annual CLE program and annual meeting from the Virginia Beach meeting of the Virginia State Bar to the Fifth Annual Legislative Update program held in Richmond on April 30th. This joint effort with the VBA Health Law Section attracted 130 pre-registrants.

Walt Sowers organized our CLE portion of the program. Tom Spahn, a noted expert in legal ethics, spoke on the ethical aspects of lawyer marketing and the Section also sponsored a panel discussion on an "Anatomy of a Peer Review Proceeding" that featured Greg St. Ours, Bob Adams and a practicing physician, Dr. Jon Palmintier.

Following the Legislative Update program, the Section held a brief business meeting and the following persons were elected to a four-year term on the Section's Board of Governors: Brian O. Dolan of Kaufman & Canoles in Norfolk; John E. Oliver, Deputy City Attorney for the City of Chesapeake and Elaine Solomon Bernstein, Director of Clinical Research, Mobile Respiratory Assessment in Charlottesville.

Walter P. Sowers, II of Warton Aldhizer & Weaver PLC in Harrisonburg will Chair the Section during 2003-2004. John C. Bilzor of Hofheimer Nusbaum, P.C. in Norfolk will serve as Vice-Chair. Stephen C. McCoy of WilliamsMullen in Richmond will edit The Virginia Health Lawyer newsletter and will be the Section's Secretary. I have high confidence in all three of these lawyers and believe that they will serve us well in the years to come.

We express our appreciation to and congratulate the following retiring members of our Board of Governors for their service: James L. Banning, Robert F. Donnelly, Jr. and Dorthula H. Powell.

The online publication of three issues of *The Virginia Health Lawyer* on the Section's website, <http://vsb.vipnet.org/sections/hl/>, continued to be a major activity during 2002-2003. My thanks to all of the contributing authors who worked so hard to make this publication "news you can use". A special acknowledgement goes to John Bilzor for the idea that the newsletter start publishing casenotes on Virginia health law cases that might

be of interest to our members. In order to be sure that our members knew when the newsletter was posted to the website, a memorandum regarding each issue was sent to the membership describing the articles in each issue.

Pat Devine, the leading VBA organizer for the Fifth Annual Legislative Update, also found time to make a significant contribution to our Section this year by undertaking an update of the "Principles of Cooperation for Physicians and Attorneys in the Commonwealth of Virginia". These Principles, a joint project of our Section and the Medical Society of Virginia, were last revised in 1993. Pat assembled an ad hoc committee that solicited views from the plaintiffs' bar, the defense bar and the judiciary.

Several steps were taken this year to raise the profile of our members. The next edition *Virginia Business* magazine's "Legal Elite" will contain a section on health law for the first time. The April issue of that magazine featured an article on the evolution of health law as a specialty in Virginia. Additionally, our Section will be responsible for the theme in the June/July 2004 issue of the Virginia State Bar magazine, *Virginia Lawyer*.

A Compendium describing and providing contact information for Virginia Health Care Trade Associations and Regulatory Agencies was posted to the Section's website. Thanks to Steve McCoy, Marie Graham, Molly Evans and Pat Devine, an update of this Compendium is underway and should be completed by the Fall.

Special thanks go to Robyn Ellis who, as our Section Webmaster, updated the Section's website and played a key role in posting *The Virginia Health Lawyer* newsletter to the website.

All in all, the Health Law Section continued to make good progress in providing services to our members and in promoting health law as a recognized legal specialty.

It has been my great pleasure and honor to serve as your Chair. My sincerest thanks go to the Board of Governors and to the many other Section members who have been primarily responsible for the positive steps taken during 2002-2003. It is my firm belief that the Section's best years are still ahead of it and I will look forward to seeing that expectation fulfilled.

Virginia's New Rules for Health Care Practitioner Disciplinary Proceedings

By Patrick C. Devine, Jr., Esquire
Hofheimer Nusbaum, P.C.

&

Karen W. Perrine, Esquire, Deputy Executive Director
Virginia Board of Medicine

Introduction

Amid growing public discussion over the manner in which the Virginia Board of Medicine disciplines its licensees, the Virginia General Assembly adopted House Bill 1441 during the 2003 Session substantially to revamp the procedures and standards that apply in connection with disciplinary proceedings of the Board of Medicine ("Board") and the other health regulatory boards, and the reporting obligations imposed on certain practitioners and institutional providers.¹ The legislation, spearheaded by freshman Delegate Winsome E. Sears of Norfolk, was sparked in large measure by a series of articles published in *The Virginian-Pilot* newspaper criticizing the efficacy of the Board of Medicine in disciplining doctors. Some of those criticisms were reflected in a 1999 study conducted for the General Assembly by the Joint Legislative Audit and Review Commission ("JLARC"), which found that "the Board of Medicine does not adequately protect the public from substandard care by physicians."²

The need for, and manner of, any reform has been the subject of considerable debate over the last year. The final legislation resulted from lengthy negotiations among Delegate Sears as the bill's patron, the Medical Society of Virginia ("MSV"), the Virginia Hospital & Healthcare Association ("VHHA"), the Department of Health Professions ("DHP"), JLARC staff and other affected parties. The final legislation reflects the attempt to balance the sometimes competing interests of practitioners, institutional providers, the thirteen health regulatory boards of DHP, and the general public. That consensus is reflected in the final version of HB 1441, which was unanimously passed by both the House and the Senate.

The new legislation is designed to (i) enable the Board to take a more active role in disciplining physicians and other licensees for substandard care, (ii) expedite the disciplinary process by improving the quantity, quality and timeliness of information reported to the health regulatory boards, (iii) permit confidential settlement of less egregious infractions by all thirteen health regulatory boards and (iv) improve the system for monitoring the overall performance of DHP and the health regulatory boards. Following is a summary of the more important aspects of this legislation.

Standard of Care

One of the more significant aspects of the legislative discussions involved the establishment of a new standard of conduct that may subject a licensee of the Board, and the Board of Physical Therapy, to disciplinary action.³ Under prior law, a practitioner's patient care activities were only subject to sanction by the boards if they resulted from conducting the practice "in such a manner as to be a danger to patients" or "gross ignorance or carelessness in . . . practice, or gross malpractice."⁴ This gross negligence standard has now been replaced by a lower "simple negligence" standard that permits the boards to sanction a practitioner based on a single instance of "intentional or negligent conduct in the practice of any branch of the healing arts that causes or is likely to cause injury to a patient or patients."⁵ The Board supported this change in the statutory scheme. This new standard will apply to conduct occurring on or after the July 1, 2003, the effective date of the legislation.

A concern was raised that this lower standard could result in a disproportionate allocation of the limited resources of the Board to address minimal patient care mistakes by otherwise apparently competent practitioners that are not likely to recur and that many believe are better left to the malpractice system for resolution. The fiscal impact statement that accompanied the legislation anticipated that the change in the standard, combined with increased reporting as discussed below, could result in approximately 1,000

additional complaints annually, which, in turn, could necessitate the hiring of an additional 27 employees by DHP at an annual cost of almost \$1.7 million.

Although the new legislation affords no direction on the issue, the Board presumably will be permitted to exercise an appropriate degree of prosecutorial discretion in determining which standard of care cases to pursue.

Confidential Consent Agreements

The new law affords practitioners, their counsel, and all of the health regulatory boards a valuable new tool for addressing comparatively less serious misconduct in a manner that both protects the general public and treats the practitioner fairly under the circumstances. DHP and the Board viewed this provision as an important complement to the change in the statutory standard for disciplinary action.

By way of background, two existing federal regulations and two separate state systems address the reporting of adverse disciplinary actions against a practitioner by any of the health regulatory boards. Depending on the nature of the disciplinary action, reports under the two federal regulations are filed either with the National Practitioner Data Bank ("NPDB")⁶ or the Healthcare Integrity and Protection Data Bank ("HIPDB").⁷ In addition, two separate state reporting systems exist. First, DHP posts on its internet site (www.dhp.state.va.us) a

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Recent Case Decisions list regarding licensees of all thirteen health regulatory boards. Also, the Board posts on its internet profiling system for doctors of medicine, osteopathy and podiatry (www.vahealthprovider.com) all notices and orders issued by the Board, including when allegations are dismissed, as Virginia law specifically provides that all notices and orders are public documents.⁸

These reporting obligations may have unintended adverse consequences, as many managed care plans will automatically exclude a practitioner from the plan's networks for most adverse Board actions, including a censure or reprimand,

except those involving a matter viewed as purely "administrative" in nature, and hospital medical staffs and health regulatory boards in other jurisdictions may take reciprocal adverse actions as well.

For example, when a physician fails to follow appropriate prescriptive protocols, the Board may conclude that the best way to protect the public and to improve the physician's practice patterns is to require that the physician attend a CME course on appropriate documentation and prescriptive practices. If such a decision is publicly reportable, it may, in effect, operate as a suspension or revocation because managed care plans may use it as a basis to terminate the practitioner's essential managed care plan participation agreements. In other self-regulated professions such as accounting, engineering and law, private reprimands are a valuable regulatory tool with few, if any, unintended economic consequences. Even public disclosure of corrective action by the regulatory board in those professions will not automatically cause the loss of contracts that are essential to the professional's business.

Over the years, the Board has been cognizant of the unintended adverse economic consequences that may result from a minor sanction or a corrective action where public safety was not compromised. The only legislative response to date has been an amendment to the law regulating the state employees' health plan to provide that networks in the plan that utilize "preferred providers shall not exclude any physician solely on the basis of a reprimand or censure" from the Board.⁹ The Managed Care Health Insurance Plan ("MCHIP") regulations also afford practitioners a modicum of due process if a managed care plan proposes to exclude them for quality of care considerations.¹⁰

As a result of discussion at its June 2002 meeting, the Board convened a workshop in September 2002 to discuss the disciplinary process in general and, specifically, the need for mechanisms other than administrative proceedings to handle cases that were of some concern but did not appear to warrant disciplinary action. The Board envisioned a remedy that would afford an alternative to disciplinary action and would enhance public safety by improving the skills of the practitioner. Further, the Board desired an efficient

mechanism to handle certain issues -- such as failure to complete continuing education requirements -- outside of the current administrative process to conserve limited adjudicatory resources.

The terms and consequences of the confidential consent agreements were heavily debated during the legislative process, and the resulting compromise appears to strike a practical balance between the interests of the public and the practitioner. Under appropriate circumstances, a health regulatory board is now permitted "to request and accept from a . . . practitioner, in lieu of disciplinary action, a confidential consent agreement . . . which shall be subject to [statutory] . . . confidentiality provisions . . ." ¹¹ Further, the bill expressly provides that a confidential consent agreement is "in lieu of disciplinary action" and "shall not be considered either a notice or order of any health regulatory board . . ." ¹² Thus, the confidential consent agreement is designed to foster practitioner cooperation and improvement to enhance public safety while reducing the possibility of unintended economic consequences for the practitioner.

The confidential consent agreement will not, however, result in the underlying misconduct being swept under the rug, as it "may be considered by a board in future disciplinary proceedings." ¹³ Further, since it "shall include findings of fact and may include an admission or finding of a violation," ¹⁴ the regulatory board will not need to relocate witnesses and evidence long after the violation has occurred in the event it needs to revisit the practitioner's admittedly inappropriate actions at a later date.

To strike a balance with the public interest, the new law provides that a "confidential consent agreement shall be entered into only in cases involving minor misconduct where there is little or no injury to a patient or the public and little likelihood of repetition by the practitioner." ¹⁵ Further, a confidential consent agreement is not permitted

if there is probable cause to believe that the practitioner has (i) demonstrated gross negligence or intentional misconduct in the care of patients or (ii) conducted his practice in such a manner as to be a danger to the health and welfare of his patients or the public. ¹⁶

"The new law affords practitioners, their counsel, and all of the health regulatory boards a valuable new tool for addressing comparatively less serious misconduct in a manner that both protects the general public and treats the practitioner fairly under the circumstances."

While some of the standards contained in that condition are not clearly defined, the language is intended to afford appropriate protection to the public against truly incompetent practitioners.

Finally, the new law does not permit the entry into more than two confidential consent agreements involving a standard of care violation by any one practitioner during any 10-year period "unless the board finds that there are sufficient facts and circumstances to rebut the presumption that the disciplinary action be made public."¹⁷

Reporting

The new legislation changes the reporting obligations of health care institutions (including hospitals and nursing homes), malpractice carriers and practitioners that become aware of a potential infraction under Va. Code §§54.1-2906 and 2909. The reporting obligations under these two statutes are sometimes confused because they apply to different (though partially overlapping) classes of players in the health care field and because the types of licensees, matters to be reported, and potential sanctions also differ.

Virginia Code §54.1-2906 requires "hospitals and other health care institutions" to report certain conduct by any person licensed by any of the 13 health regulatory boards. On the other hand, Va. Code §54.1-2909 places a reporting obligation on licensed health care institutions, practitioners, malpractice carriers and others, but this reporting obligation applies only to conduct by persons licensed by the Board of Medicine.

Subject to the confidentiality provisions under federal substance abuse regulations, hospitals and other health care institutions are required, under Va. Code §54.1-2906, to report within 30 days: (a) "information . . . indicating [the] professional is in need of treatment or has been committed or admitted . . . for treatment of substance abuse or a psychiatric illness which may render [him] . . . a danger to himself, the public or his patients;" (b) of a determination, "after reasonable investigation and consultation as needed with the appropriate internal [disciplinary] boards or

committees . . . , [that there is] a reasonable probability [of] unethical, fraudulent or unprofessional conduct;" (c) "any disciplinary action, including denial or termination of employment [or of] . . . privileges or restriction of privileges while under investigation or during disciplinary proceedings, taken . . . as a result of . . . intentional or negligent conduct that . . . is likely to cause injury . . . , professional ethics, professional incompetence, moral turpitude or substance abuse, . . . with the report to be filed within 30 days of written communication to the professional notifying him of the disciplinary action;" and (d) "voluntary resignation . . . [,] restriction or expiration of privileges while . . . under investigation or [while he] is the subject of disciplinary proceedings . . . related to" any such matter.¹⁸ Reports may need to be filed within five days in the case of certain commitments or admissions.¹⁹

The timing of the required reports under the new legislation was very important to the Board. The Board's position was that reports needed to be made once an initial determination or recommendation was made by the medical staff, or a committee thereof, to take or impose any adverse action, and that the report should not wait until the due process provisions of the hospital bylaws, and all appeals, were exhausted. The new law adopted the Board's position on that issue.

Virginia Code §54.1-2909 requires that reports be filed in the case of (a) disciplinary actions in other states; (b) malpractice settlements and judgments; and (c) "evidence that indicates a reasonable probability that a [practitioner] . . ." (i) "may be incompetent," (ii) "has engaged in intentional or negligent conduct that causes or is likely to cause injury . . . [or] unprofessional conduct," or (iii) "may be mentally or physically unable . . . safely [to] . . . practice. . . ." The report must be filed within "30 days from the date of . . . occurrence."²⁰

For the first time, potential civil penalties for failure by licensees, hospitals and other mandated reporters to make a timely report of a reportable event were authorized, with the penalty being \$25,000 or \$5,000, depending on the context.²¹ If the civil penalties are ordered and not timely paid, an institution may lose its license.

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One area of contention among the stakeholders involved the substance of the report that must be made by a hospital and other health care institutions as a result of its medical staff peer review activities. One justification for an enhanced reporting obligation was to facilitate DHP's investigative process and to improve the health regulatory board's ability to act quickly. Early versions of the bill potentially would have required hospitals and health care institutions to share with DHP and the health regulatory boards virtually all of the institutions' investigative information and incident reports. The concern of the provider community was that the potential quality enhancing aspects of the peer review process under existing law might be undermined if all confidentiality and privilege protections were lost.

In a December 3, 2002, letter to Delegate Sears, representatives of the MSV and the VHHA explained their position regarding the benefits of existing hospital peer review protocols in improving quality of care and the role that confidentiality plays in that process. The DHP and the Board understood those concerns, but believed that access to certain information and documentation, such as contemporaneous incident reports by nursing staff, were necessary to conduct an appropriate and successful investigation.

The resulting compromise tempers the scope of the peer review information that must be reported, while still affording DHP a significant head start in the investigative process.²² Specifically, the hospital or other health care institution's required written report shall:

- give the name and address of the person who is the subject of the report,
- fully describe the circumstances surrounding the facts required to be reported,
- include the names and contact information of individuals with knowledge about the facts required to be reported and the names and contact information of individuals from whom the hospital or health care institution sought information to substantiate the facts required to be reported,
- include all relevant medical records if patient care or the health professional's health status is at issue, and
- provide notice to the Board that the institution has submitted any required report to the National Practitioner Data Bank.²³

Further, it is specifically stated that

[t]his section shall not be construed to require the hospital or health care institution to submit any proceedings, minutes, records or reports that are privileged under §8.01-581.17, except that the provisions of §8.01-581.17 shall not bar (i) any report required by this section or (ii) any requested medical records which are necessary to investigate unprofessional conduct . . . [, and u]nder no circumstances shall compliance with this section be construed to waive or limit the privilege provided in Section §8.01-581.17.²⁴

The new legislation confirms that there is no reporting obligation for any matter "if the person or entity has actual notice that the same matter has already been reported to the Board."²⁵ Appropriate NPDB reporting is also required, and for certain reports, sending the Board a copy of the NPDB report may satisfy the reporting obligation.²⁶

A new provision requires the hospital or health care institution to "give the health care professional who is the subject of the report an opportunity to review the report [, and] the health professional may submit a separate report if he disagrees with the substance of the [institution's] report."²⁷ Importantly, the broad immunity from liability to those persons who properly make reports is now also afforded to any person providing information "pursuant to an investigation."²⁸

Finally, the new law contains a provision that requires the reporting of any malpractice settlement, where, formerly, the law required reporting only when there were two settlements within a three-year period.²⁹ The new law also adds language confirming the Board's historic position that any disciplinary action arising from a malpractice settlement report must be based on the underlying conduct, not the fact of the malpractice settlement itself.³⁰

Monetary Penalty

The new law increases the monetary penalty that a health regulatory board may impose on a practitioner who violates any statute or regulation pertaining to that board, and is not criminally prosecuted. A practitioner may be fined up to \$5,000 per violation, instead of \$1,000 under prior law.³¹ This penalty is separate from those that may be imposed on practitioners or institutions that fail timely to report information as discussed above.³²

Confidentiality of Certain Information

All information received and maintained by a health regulatory board in connection with a possible disciplinary proceeding shall be strictly confidential, and may only be disclosed in certain enumerated circumstances.³³ The new law changes the current provisions as follows:

- the prohibition on the use of any confidential material in any malpractice proceeding or related discovery has been expanded to any "civil proceeding,"
- the ability to share information with law enforcement relating to violations of state drug laws has been expanded to all "criminal matters," and
- the standard of "for good cause arising from extraordinary circumstances" has been added to the provision permitting the release of information "pursuant to an order of a court of competent jurisdiction."³⁴

Revocation and Reinstatement

The new law precludes any practitioner regulated by any of the health regulatory boards whose license has been revoked from applying for reinstatement for a period of three years.³⁵ Under prior law, a licensee of the Board of Medicine could not reapply for reinstatement until one year after revocation; however, there was no statutory limitation imposed on licensees of the other health regulatory boards.³⁶

Unlicensed Activity

Under prior law, the only remedy available to DHP and the health regulatory boards for addressing unlawful practice by a person not licensed by any health regulatory board was to seek criminal sanctions or an injunction and civil penalties from a circuit or general district court. In response to comments in the JLARC report, the new law authorizes the Director of DHP to issue a summons to a person who violates the laws and regulations governing the unlicensed practice of the professions regulated by DHP.³⁷ Failure to obey the summons or discontinue the unlawful acts may result in criminal action.³⁸

Accountability

In order to monitor the performance of DHP and the health regulatory boards under this new law and to determine whether further legislative action may be necessary, the new

law modifies the requirements of the biennial report that the Director of the Department of Health Professions must present to the General Assembly.³⁹

First, the Director's report must be made "for each of the health regulatory boards."⁴⁰ Second, "the report shall contain for each profession regulated by a health regulatory board the number of cases in which a sanction was imposed."⁴¹ Third, the "sanctions shall be reported by category of violation for each profession, and [one] reported category shall be cases involving standard of care violations."⁴² Finally, the report must include

- (i) case processing time standards for resolving disciplinary cases, (ii) an analysis of the percentage of cases resolved during the last 2 fiscal years that did not meet such standards, (iii) a 6-year trend analysis of the time required to process, investigate and adjudicate cases, and (iv) a detailed reporting of staffing levels for the 6-year period for each job classification that supports the disciplinary process.⁴³

The Director's initial biennial report shall require a four-year, rather than six-year, trend analysis and staffing level report.

Composition of the Board of Medicine

Legislation sought by the Board and enacted by the 2001 General Assembly increased the number of citizen members on the Board from two to four.⁴⁴ The new law increases the size of the Executive Committee from seven to eight and requires that at least two of the members be citizen members.⁴⁵ The Board supported this change.

Burden of Proof

The burden of proof necessary to find a violation of the Code that currently is followed by the health regulatory boards is the "clear and convincing" standard.⁴⁶ Many who were critical of the actions of the health regulatory boards had advocated for a lower "preponderance of the evidence" standard. Indeed, the Board sought legislation this session to lower the standard in cases that did not result in revocation or suspension; however, the new legislation does not lower the burden of proof, and the clear and convincing standard continues to apply.

Conclusion

What began as a high-profile, sometimes acrimonious and divisive public relations and legislative battle evolved through education and cooperation into what appears to be a balanced approach to improved practitioner self-regulation. All stakeholders participated equally in a process marked by patience and a willingness to listen and compromise. Whether, in practice, the new law will work to the satisfaction of the various parties remains to be seen. However, it is important that practitioners and health care institutions, and their counsel, understand these new rules when developing strategies to address and comply with the new practitioner disciplinary process and requirements.

This article was prepared as of May 1, 2003, and is for informational purposes only. It is not intended as legal advice and is not intended to reflect the formal position of the DHP or any of its health regulatory boards.

¹Identical legislation introduced in the Senate, SB 1334, passed unanimously as well and was the product of two merged bills introduced by Senators William Bolling and Creigh Deeds. HB 1441 can be accessed at <http://legis.state.va.us>.

²The JLARC website link to the report is: <http://jlarc.state.va.us/Summary/Rpt233/health.htm>

³The Board of Medicine licensed physical therapists until July 1, 2000 when the Board of Physical Therapy was established (see Section 54.1-3473 et seq.) The laws regarding physical therapy, including grounds for disciplinary action, were adapted from the Board of Medicine's laws.

⁴See Va. Code §54.1-2914(A)(8) and 2915(A)(4) under prior law. Unless otherwise stated, the statutes referred to in these footnotes are intended to reflect the statutory changes adopted by the General Assembly during the 2003 Session which become effective on July 1, 2003.

⁵Va. Code §2915(A)(4).

⁶42 U.S.C. §11132(a)(1)(A) and 45 C.F.R. §60.3 and 60.8(a)(1) and (2). The NPDB regulations require reports of "any action ...[w]hich revokes or suspends (or otherwise restricts) a physician's or dentist's license (emphasis added)." Since the opening of NPDB in 1990, DHP has reported any order containing an additional term or condition imposed on a practitioner, however minor, in connection with the retention

of his or her license which is not likewise imposed on all other licensed practitioners, as a "restriction" of the license for the purposes of NPDB, although some attorneys may disagree with this interpretation.

⁷42 U.S.C. §1320(a)-7e(b)(1) and (g)(1)(A)(iii)(I) and (III) and 45 C.F.R. §61.3 and .7. The HIPDB reporting provisions would not appear to be implicated by a confidential consent agreement. These regulations only require reporting of "final and adverse actions (not including settlements in which no findings of liability have been made)...." "Final adverse actions" are defined as "actions by [a health regulatory board]...including (I) formal or official actions, such as revocation or suspension..., reprimand, censure or probation...[or] (III) any other negative action or finding...that is publicly available" even if no sanction is imposed. A confidential consent agreement should not be considered a "formal or official action" under subsection (I), as the confidential consent agreement cannot impose any of the five separate sanctions specifically listed therein. Finally, the "other negative action or finding" concept in subsection (III) is limited to those determinations which are "publicly available," and the Virginia statute expressly states that confidential consent agreements are not to be made publicly available.

⁸See §54.1-2400.2(F) and 2910.1(A)(12). See also 18 VAC 85-20-290(B).

⁹Va. Code §2.2-2818(F).

¹⁰12 VAC 5-408-170.

¹¹Va. Code §54.1-2400(14).

¹²*Id.* This provision obviates the need to report an agreement on the state web sites. Further, although the Virginia Attorney General's Office, which coordinates the reporting obligations of the health regulatory boards under the NPDB and the HIPDB regulations, has not, as of the date of this publication, taken a final position on the possible need to report certain confidential consent agreements, it appears the bill's drafters intended the "consent agreements" to be "confidential," except in the limited circumstances expressly contemplated in the bill. An analysis of the language of these reporting regulations in the context of the language of the bill could support the absence of a reporting obligation to the federal data banks.

¹³Va. Code §54.1-2400(14).

¹⁴*Id.*

¹⁵*Id.*

¹⁶*Id.*

¹⁷*Id.*

¹⁸Va. Code §54.1-2906(A). See Va. Code §54.1-2906(E) and 42 U.S.C. §290dd-2.

¹⁹Va. Code §54.1-2906(B).

²⁰Va. Code §54.1-2909.

²¹Va. Code §§2505(21), 2906(F), 2908(G) and 2909(G). Compare Va. Code §54.1-2401 concerning penalties for violation of a statute or regulation discussed in the text accompanying footnote 32, *infra*. See also Va. Code §54.1-111(B).

²²See Va. Code §§54.1-2400.2(B) and (C), 2906(A) and 2909(D).

²³Va. Code §54.1-2906.

²⁴Va. Code §54.1-2906(A).

²⁵Va. Code §§54.1-2906(A) and 2909(C).

²⁶Va. Code §§54.1-2906(A) and 2909(A). See also Va. Code §54.1-2908(C).

²⁷Va. Code §54.1-2906(A).

²⁸Va. Code §§54.1-2906(D), 2908(E) and 2909(E).

²⁹Va. Code §54.1-2909(A)(3).

³⁰Va. Code §54.1-2909(H).

³¹Va. Code §54.1-2401.

³²See discussion of Va. Code §§54.1-111(B), 2906(F) and 2908(G) in the text accompanying footnote 21, *supra*.

³³Va. Code §54.1-2400.2.

³⁴*Id.*

³⁵Va. Code §54.1-2408.2.

³⁶See former Va. Code §54.1-2921. During the 2002 General Assembly session, the Board unsuccessfully sought the ability to impose a period of revocation of between one and five years.

³⁷Va. Code §54.1-2506(C). See also Va. Code §54.1-111(B).

³⁸*Id.* A fine is also a permissible sanction.

³⁹Va. Code §54.1-2400.3. See Va. Code §54.1-114.

⁴⁰Va. Code §54.1-2400.3.

⁴¹*Id.*

⁴²*Id.*

⁴³*Id.*

⁴⁴Va. Code §54.1-2911.

⁴⁵*Id.*

⁴⁶See 1979-80 Opinion of Office of Attorney General at 168.

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The Virginia Birth Injury Program: Challenges of Adolescence

By K. Marshall Cook, Esquire
Hirschler Fleischer, P.C.

On July 1, the Virginia Birth-Related Neurological Injury Compensation Program celebrates its 16th birthday and is experiencing the same growing pains that are encountered by most adolescents. Legislation establishing the Program was enacted by the 1987 Session of the General Assembly. Children whose condition satisfies the statutory definition of "birth-related neurological injury" in Va. Code §38.2-5001 and other criteria detailed in Va. Code § 38.2-5008 are entitled to significant benefits from the Program.¹ When the Birth Injury Act is accessed for these benefits, other "rights and remedies" otherwise available, including medical negligence actions, are foreclosed by statute.²

For an entity whose primary original purpose was to stabilize the professional liability insurance environment for Virginia physicians delivering obstetrical services, the Program's minimal staff now manages the equally vital task of administering benefits for an ever-growing number of neurologically injured children. In the past year, the Program was the subject of a study by the Joint Legislative Audit and Review Commission (JLARC) that resulted in significant legislation enacted by the 2003 Session of the Virginia General Assembly, endured a barrage of newspaper articles challenging its processes and its very purpose, and lost a hard-working and dedicated Executive Director whose *raison d'être* was to see to it that the children the Program serves were properly cared for. This article describes the primary provisions of the 2003 legislation.

The Program's Board of Directors will be a relatively new and inexperienced group when the 2003 legislation is implemented. No board member will have served longer than 3½ years. Likewise, the Program's Executive Director

now enjoys a little more than one year of experience and, thankfully, a proficient and devoted staff, all of whom do a good job of administering the Program and its benefits.

The next twelve months will be as challenging for the Program's board and staff as any Program board or staff ever has experienced. While performing their normal function of caring for the 68 children the Program now serves (this number grows regularly), the Program's Board of Directors and its seven current employees also will coordinate two studies the 2003 legislation requires, become conversant with the Virginia Freedom of Information Act, the Virginia Public Procurement Act and the Administrative Process Act, welcome and train several new board members³, including the Program's only remaining physician member, and implement the remaining requirements of the 2003 legislation.

An unfortunate result of the 2003 legislation is that the Program now has a number of mandates, all of which will increase its expenses, but none of which will increase its revenues.⁴ In fact, the Program receives no state or other government funding. It is axiomatic that Program funding will be a topic for debate at the 2004 General Assembly.

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Notice, Liability and Award Issues

Several provisions in the 2003 legislation involve liability and award issues for Program claimants. The Workers' Compensation Commission is authorized to award up to \$100,000 to the parents or legal guardian of an injured infant covered under the Virginia Birth-Related Neurological Injury Compensation Program who dies within 180 days of

birth. See Va. Code § 38.2-5009.1. This award is in addition to any other award providing compensation under Va. Code § 38.2-5009. Presumably, most of the petitions concerning this maximum \$100,000.00 award will involve premature infants and, as a result, it will be more difficult to satisfy the statutory definition of "birth-related neurological injury"⁵ to support these awards. Even so, the Program is obligated to defend these new claims, some of which necessarily will be awarded, and potentially pay attorneys' fees even for those claims for which an award is not made.⁶

The legislation further provides that a mother is not subject to the Program's exclusive remedy provision with respect to physical injuries she suffers during delivery that are separate and distinct from the infant claimant's injury.⁷

Although the Program has done a number of things in the past several years to increasingly publicize its existence, including instituting a web site at <http://www.vabirthinjury.com> containing such items as the Program's current statutes, guidelines, and a link to the recent JLARC study materials, the 2003 legislation further requires physicians, midwives, and hospitals to advertise the Program and its processes. For the first time in this writer's recollection, an entity that receives no state funding is made subject to the Virginia Freedom of Information Act (FOIA) and further is required to implement procedures consistent with the Public Procurement Act and the rulemaking provisions of the Administrative Process Act.⁸

A new statute, Va. Code § 38.2-5002.2, provides that the following records of the Program are confidential and, therefore, presumably may not be disclosed pursuant to a FOIA records request even if the Program's board does not exercise the new exemption provided in Va. Code § 2.2-3705(A)(82):

- records subject to the attorney-client privilege
- medical and mental records of claimants obtained by the board of directors in the course of administering the Program
- records concerning deliberations of the board of directors in connection with specific claims
- reports of expert witnesses retained by the board of directors that have not become part of the record before the Virginia Workers' Compensation Commission

- all records required to be kept confidential by federal law

The statute specifically prohibits officers, agents or employees of the Program from disclosing, directly or indirectly, any such confidential record or information "except as herein authorized."

Physicians, hospitals, and nurse midwives who provide obstetrical services now are required to provide written notice to their patients whether they are participants in the Program.⁹ All hospitals also must provide to the mother or

other appropriate person a brochure concerning the Program with post-partum materials if the infant was hospitalized in a neonatal intensive care unit.¹⁰

Additional Procedural Requirements

Other provisions of the 2003 legislation are more procedural. For instance, hospitals are required to release fetal monitoring strips to the Program or to an injured infant's legal representative, and the failure to provide

this information will create a rebuttable presumption of fetal distress in proceedings before the Workers' Compensation Commission to determine whether a claimant should be admitted into the Program.¹¹

Physician review panel duties now will rotate on a case-by-case basis among Eastern Virginia Medical School, the University of Virginia School of Medicine, and the Medical College of Virginia, and the review panel's report is required to be mailed to the Program and all parties within 60 days after the original petition is filed. The statute further requires the review panel's report to contain

a detailed statement of the opinion of the panel's members regarding whether the infant's injury does or does not satisfy each of the criteria of a birth-related neurological injury enumerated in such term's definition in § 38.2-5001. The report shall include the panel's basis for its determination of whether each such criteria was or was not satisfied. In addition, the report shall include such supporting documentation as the board of directors of the program may reasonably request.¹²

The Department of Health Professions or Department of Health, as appropriate, are required by the 2003 legislation

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to investigate the conduct of a participating physician or hospital in claims filed with the Commission for conduct that may give rise to disciplinary action. A copy of any notice or order issued by the Board of Medicine in such cases is required to be mailed to the petitioner or claimant.

The Program's board of directors is required to consult semiannually with the chief investment officer of the Virginia Retirement System regarding fund management strategies and asset allocations, and the Program's investment advisor shall provide annual statements explaining the expected returns on its equities and fixed income portfolios.

The Program's board is directed by the 2003 legislation to (a) develop and implement a policy on handicapped accessible housing, (b) study and develop options for revising fees for participating providers, and (c) maintain a list of Program participants and, with consent, make the list available to other claimants.

As discussed earlier, the implementation of these significant legislative mandates, while caring for the children this Program is required to serve, will challenge an already hard-working board of directors and staff. The important purposes this Program serves should never be overlooked as it moves from its adolescence into financial and administrative maturity.

¹These benefits are detailed in Va. Code § 38.2-5009 and include:

1. Actual medically necessary and reasonable expenses of medical and hospital, rehabilitative, residential and custodial care and service, special equipment or facilities, and related travel, such expenses to be paid as they are incurred. However, such expenses shall not include:
 - a. Expenses for items or services that the infant has received, or is entitled to receive, under the laws of any state or the federal government except to the extent prohibited by federal law;
 - b. Expenses for items or services that the infant has received, or is contractually entitled to receive, from any prepaid health plan, health maintenance organization, or other private insuring entity;
 - c. Expenses for which the infant has received reimbursement, or for which the infant is entitled to receive reimbursement, under the laws of any state or federal government except to the extent prohibited by federal law; and
 - d. Expenses for which the infant has received reimbursement, or for which the infant is contractually entitled to receive reimbursement, pursuant to the provisions of any health or sickness insurance policy or other private insurance program.
2. Expenses of medical and hospital services under subdivision 1 of this section shall be limited to such charges as prevail in the same community for similar treatment of injured persons of a like standard of living when such treatment is paid for by the injured person.

3. Loss of earnings from the age of eighteen are to be paid in regular installments beginning on the eighteenth birthday of the infant. An infant found to have sustained a birth-related neurological injury shall be conclusively presumed to have been able to earn income from work from the age of eighteen through the age of sixty-five, if he had not been injured, in the amount of fifty percent of the average weekly wage in the Commonwealth of workers in the private, nonfarm sector. The provisions of § 65.2-531 shall apply to any benefits awarded under this subdivision.
4. Reasonable expenses incurred in connection with the filing of a claim under this chapter, including reasonable attorneys' fees, which shall be subject to the approval and award of the Virginia Workers' Compensation Commission.

²See Va. Code § 38.2-5002(B).

³The 2003 legislation replaces the board's non-participating physician representative with a citizen member with professional experience working with the disabled community. Two of the other citizen members of the board are required to have a minimum of five years of professional investment experience, one is required to have professional experience working with the disabled community, and one shall be the parent of a disabled child. Citizen members of the Program's Board of Directors may not have children or relatives who are claimants or who have been awarded benefits under the Virginia Birth-Related Neurological Injury Compensation Act. See Va. Code § 38.2-5016(C)(1)(a).

⁴The Program's Board of Directors' authority to reduce the annual participating physician and hospital assessments in Va. Code § 38.2-5016(F) was eliminated.

⁵See Va. Code § 38.2-5001.

⁶The Commission now may award an *unsuccessful* petitioner's reasonable attorneys' fees and other expenses incurred in filing a claim in good faith. See Va. Code § 38.2-5009(B).

⁷See Va. Code § 38.2-5002(B).

⁸See Va. Code § 38.2-5002.1(B), (C), and (D).

⁹See Va. Code § 38.2-5004.1(A).

¹⁰See Va. Code § 38.2-5004.1(B).

¹¹Compare Va. Code § 38.2-5004(E) with §38.2-5008(A)(1)(b).

¹²Va. Code § 38.2-5008(C).

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Federally Qualified Health Centers: A Viable Alternative in the Current Crisis in Virginia Health Care?

By Molly Shuttleworth Evans, Esquire

&

Marcie H. Zakheim, Esquire

While the number of underinsured and uninsured Virginians continues to rise,¹ the current budget crisis in the Commonwealth means that resources allocated to providing health care to those people who need it most have continued to diminish. Meanwhile, each year health care providers in Virginia face more and more restrictions and regulations while the cost of doing business continues to escalate. From hospital outpatient clinics that are unable to turn a profit to OB/GYNs who can no longer afford the cost of their malpractice insurance, our health care provider clients are looking for alternatives.

As attorney-advisors, it is important for us to offer viable solutions to our health care provider clients who find themselves struggling in today's health care environment. It is also important for us to acknowledge that Virginia needs to find a way to respond to the health care needs of the ever-growing population of underinsured and uninsured in the Commonwealth. In an attempt to seek out alternatives for our clients, we should be aware of the benefits and challenges of the federally funded health center program.

What is an FQHC?

Federally Qualified Health Centers ("FQHCs") are public or private, charitable, tax-exempt nonprofit organizations that either (1) receive funding pursuant to Section 330 of the Public Health Service Act ("Section 330") or, (2) are determined by the Department of Health and Human Services ("DHHS") to meet all of the governance, management, financial, clinical and other organizational

requirements to receive funding under Section 330 without actually receiving such funding (*i.e.*, an "FQHC look-alike"). Section 330 funds are awarded and administered by the Bureau of Primary Health Care ("BPHC"), an agency within Health Resources and Services Administration ("HRSA") of DHHS, in order to support the FQHC's provision of a full spectrum of primary and preventative health care services, as well as essential ancillary and enabling services, (including translation, transportation, outreach, eligibility assistance and case management) to medically underserved and uninsured populations.² The BPHC provides grant funding to a number of different health center programs including: Community Health Centers, Migrant Health Centers, Health Care for the Homeless Programs, Public Housing Primary Care Programs and Urban Indian and Tribal Health Centers. FQHCs form the backbone of the so-called "safety net" primary care provider system in the United States, serving medically underserved populations, including millions of underinsured and uninsured individuals and families.

In 2001, President Bush announced the Administration's five-year initiative to *double* the number of health center "access points" by the end of FY 2006 by adding 1,200 new health center sites and to increase the number of patients treated annually from 10 million to 16 million. As a result, the health center program has expanded significantly since 2001. The funding for FY 2003 was \$1.505 billion, about \$280 million above the funding level two years ago. President Bush's FY 2004 budget requests \$1.627 billion for health centers. The FY 2004 increase would support the creation of about 120 new health centers and expand 110 existing

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sites for a total of 3,700 Health Center sites, up from 3,317 in FY 2001 before the initiative began.

What Are Some of the Key Criteria for Becoming an FQHC?

- **Must serve a Medically Underserved Area ("MUA") or Medically Underserved Population ("MUP").** MUAs and MUPs are federal designations made by HRSA for defined geographic areas/ population groups with insufficient health resources. MUAs are identified by calculating a composite index of four need indicators (poverty rate, infant mortality rate, percentage of aged population, and primary care physicians per 1,000 population) and comparing the index with national averages. Individual population groups that are in geographic areas that do not qualify as MUAs can still qualify as MUPs by using either a method similar to the composite index method discussed above or by documenting unusual local conditions that result in access barriers to medical services for that population group.
- **Must provide, directly or by contract, a comprehensive scope of preventive and primary care services, as well as enabling services, to all residents of its service area (*i.e.* all services must be available and accessible to diverse age groups), regardless of an individual's or a family's ability to pay.** The FQHC cannot provide a single service, such as dental, mental health or prenatal services.³ Further, the FQHC cannot serve a single age group (*i.e.*, children) or lifecycle (*i.e.*, geriatric only) except in the case of organizations applying under Section 330(h) to target services for homeless children and adolescents.
- **Must establish a schedule of charges that is designed to cover the FQHC's reasonable costs of operation and is consistent with locally prevailing rates or charges.**
- **Must establish a corresponding schedule of discounts, adjusted on the basis of the patient's ability to pay, for individuals or families who earn below 200% of**

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the Federal poverty guidelines (with full discounts for individuals and families who earn below 100% of poverty).

- **Must comply with the requirements and standards set forth 45 CFR Part 74 *et seq.* (or Part 92 if the applicant would be a public entity).** Part 74, *inter alia*, regulates the procurement of goods and services (as well as grant financial management systems and the acquisition and management of property) using Federal grant funds. If the FQHC receives Section 330 funds (as opposed to "look-alike" entities that do not receive grants), it must comply with these requirements and standards.
- **Must be governed by a community-based governing board.** A majority of the members of the Board must be persons who utilize the FQHC's services as their primary source of primary and preventive health care, and, who, collectively, represent the FQHC's patient population in terms of demographic factors such as race, ethnicity and gender. Good cause exceptions are available for FQHCs that receive funds only to serve a particular special population (*i.e.*, migrant/seasonal farm workers, homeless populations, or residents of public housing).
- **Non-user members of the governing board must be representative of the community served by the FQHC.** These board members should be selected for their expertise in health care delivery, community affairs, local government, finance and banking, legal affairs, trade unions, and other commercial and industrial concerns, or social service agencies within the community; *provided that*, no more than one-half of the non-user Board members may be individuals who derive more than ten percent (10%) of their annual income from the health care industry.
- **The Board must be able to autonomously exercise key authorities regarding, among other things, establishing and approving operating and service policies (*e.g.*, health care scope, location and schedule of services, quality assurance, financial, personnel), approving the**

FQHC's budget and grant application, strategic and operational planning, and the hiring of the executive director/ chief executive officer.

- Must directly employ the Executive Director and is expected to directly employ other members of the management team, including a Chief Financial Officer and a Chief Medical Officer (subject to good cause exceptions).
- Must have a *multi-disciplinary, culturally and linguistically competent* clinical staff that should include an appropriate number of physicians. FQHCs are permitted to contract for providers independently or from third parties (*e.g.*, hospitals, private practices); however, FQHCs are expected to directly employ a *majority* of their clinical providers (subject to good cause exceptions).

What Are Some of the Benefits Available to FQHCs?⁴

- **Access to Federal grants.** For FY 2003, up to \$650,000 in grant funds are available *per applicant* for "new delivery sites" for the provision of comprehensive primary and preventative health care services. These new delivery sites are called "New Access Points."⁵ According to the BPHC, there are two types of New Access Point applicants: (1) new starts and (2) satellites. A "New Start" applicant is an organization that currently does not receive Federal grant support under *any* program authorized under Section 330 of the PHSA. A "Satellite" applicant is an organization that currently receives grant support under one or more programs authorized under Section 330 of the PHSA. In order to receive New Access Point funds, Satellite applicants must propose to establish a new access point(s) (*i.e.* new site) to serve a new patient population that is outside of the applicant's approved scope of project. As April 30 was the deadline for the final FY 2003 grant funding cycle, any entities considering application as a New Access Point will have to wait until BPHC issues the application and guidance for FY 2004 funding, which is likely to occur in the fall of calendar year 2003. While the actual maximum amount of grant funds that entities will be eligible to receive is not known, it is anticipated that the number will be close to the \$650,000 that each applicant was eligible to receive in FY 2003.

In addition to grant funds available for New Access Points in FY 2003, up to \$600,000 in grant funds were available per applicant to expand capacity, thereby increasing access, in service delivery sites within an existing FQHC's approved scope of project. These sites are called "Expanded Medical Capacity" sites.⁶ In addition, for FY 2003, earmarked grants were also available to existing FQHCs to initiate or expand mental health, substance abuse, oral health and quality management services.⁷ Similar to the New Access Point funding, it is likely that FY 2004 funding will be available for Expanded Medical Capacity sites, as well as for substance abuse, mental and oral health and quality management services, and will be announced near the end of 2003 or in the beginning of 2004.

- **Access to enhanced reimbursement for Medicare and Medicaid programs.** FQHCs receive reimbursement for primary health care services under a Prospective Payment System ("PPS") (which is based on cost-based reimbursement) for Medicaid services, subject to state specific waivers, and cost-based reimbursement for Medicare services. This means that, for the most part, FQHCs will receive a significantly higher rate of reimbursement than most other health care providers.
- **Access to Federal Tort Claims Act ("FTCA") coverage.** The FQHC entity, its Board, as well as all employees and certain individually contracted health professionals, who provide services to FQHC patients within the FQHC's approved scope of project and the provider's scope of employment/contract, are eligible to be treated as Federal employees covered by the FTCA in lieu of having to purchase medical malpractice insurance (so long as the FQHC is "deemed" eligible by the Federal government). If a malpractice claim against a deemed FQHC is settled or results in a judgment against the FQHC, payment is made out of a Section-330 supported judgment fund (and not offset against the FQHC's grant). As we are all well aware, because the provider would pay no or minimal premiums (*i.e.* for gap insurance or to cover incidents occurring prior to being "deemed" eligible), FTCA coverage would significantly decrease the cost of operating a clinic or providing health care services.
- **Access to favorable pricing under Section 340B of the Public Health Service Act.** Section 340B provides

FQHCs with the opportunity to purchase certain covered outpatient prescription drugs to be used solely for FQHC patients at substantially discounted prices equivalent to Medicaid best price or better. These drugs can be distributed either by the FQHC or through a contract with a retail pharmacy.

- **Ability to participate in Disease Management Collaboratives.** FQHCs are eligible to participate in Disease Management Collaboratives. These Collaboratives can be supported by additional grant monies.
- **Access to free vaccines under the Federal Vaccine for Children Program and eligibility to participate in the Pfizer Sharing the Care Program.** The Federal Vaccine for Children Program distributes to FQHCs vaccines at no charge for either the vaccine or the delivery to the FQHC.

When Are Applications Due?

For the FY 2003 funding cycle there were three separate application deadlines during which an applicant for New Access Point funds could file: December 16, 2002, February 18, 2003 and April 30, 2003. For the most part, funding decisions are made within three to four months of application submission. April 30, 2003 was the final opportunity that applicants had to submit an application for a FY 2003 New Access Point grant. According to the BPHC, funding decisions for the April 30, 2003 applicants will be made on or before August 15, 2003.⁸

As the dates for the FY 2003 funding cycle have come and gone, health care providers should look ahead to submission of applications for the FY 2004 grant cycle. This additional time will allow providers to adequately consider structural collaboratives and other opportunities. It's never too early to start planning!⁹ As stated earlier, application deadlines for the FY 2004 grant cycle will not be announced until the 2004 Program Information Notice ("PIN") on New Access Points is issued, although the first application deadline for FY 2004 will most likely be sometime in mid-November 2003.

How Should a Virginia Health Care Provider Evaluate the FQHC Option?

There are a number of baseline factors that a health care provider should consider in order to evaluate whether applying for Section 330 New Access Point funding to become an FQHC is a viable option for the provider. Does the health care provider currently provide a comprehensive scope of primary care services to its patients? Does the provider serve a substantial number of uninsured and underinsured individuals? Is the provider located in or serving a Federally designated MUA or MUP? Does the provider have the capacity and/or desire to expand both the services it is providing and the population to which it is providing these health care services? Is the provider's service area currently served by an FQHC? Would the provider be interested in some kind of collaboration with an existing FQHC, hospital outpatient clinic, free clinic or other qualified health care provider?

"There are a number of reasons why collaboration would make sense for a health care provider new to the world of FQHCs. First, collaboration, as opposed to going it alone, would help to ensure and enhance services, as well as the continuity of care in an underserved community without duplicating the efforts of an existing FQHC. Next, collaboration with an existing FQHC would allow a health care provider to participate on some level within the FQHC framework without having to restructure to meet all of the FQHC-specific requirements."

Health care providers may want to consider contacting the Virginia Department of Health, Center for Primary Care and Rural Health and/or the Virginia Primary Care Association to discuss their potential options.¹⁰ After analyzing the criteria and benefits of the FQHC program, a health care provider may decide that collaborating with an existing FQHC may be the most viable option. There are a number of reasons why collaboration would make sense for a health care provider new to the world of FQHCs. First, collaboration, as opposed to going it alone, would help to ensure and enhance services, as well as the continuity of care in an underserved community without duplicating the efforts of an existing FQHC. Next, collaboration with an existing FQHC would allow a health care provider to participate on some level within the FQHC framework without having to restructure to meet all of the FQHC-specific requirements. For example, a hospital and FQHC could collaborate to operate the hospital's outpatient clinic: the hospital would lease the clinic space to the FQHC, and

the FQHC would purchase clinical capacity from the hospital. Also, collaboration could potentially help to shelter a health care provider from the learning curve and financial investment that would be associated with filing a New Start application. In the event that a health care provider decides to collaborate with an existing FQHC, the existing FQHC would file a New Access Point grant application to include the health care provider's practice as a Satellite site of the existing FQHC.¹¹ If a health care provider is not able to (or decides not to) collaborate with an existing FQHC, it could "go it alone" or collaborate with another qualified health care provider that may also be interested in pursuing New Start funds. However, if there is an existing FQHC in the service area, the new applicant may not compete successfully for Section 330 funding unless it can demonstrate significant unmet need in the area and appropriate linkages with the FQHC designed to minimize duplication, enhance the service continuum, and avoid the potential waste of scarce federal resources.

Any interested health care provider-client should also consider the BPHC requirements for Section 330 grant applicants.¹² First, the health care provider would need to determine whether it is located in an MUA or MUP. As the purpose of the health center program is to provide quality health care for the medically underserved, the geographic location of the potential site *must be* in or serving an MUA or MUP.¹³ If you are unsure as to whether your client's practice or clinic is in a federally designated MUA or MUP, please refer to <http://bhpr.hrsa.gov/shortage/muaguide.htm> or contact the Shortage Designation Branch of HRSA at 1-800-400-2742.

Next, a health care provider would need to evaluate and ensure that it could, either by itself or through collaboration, provide the comprehensive primary and preventive care and enabling services required of FQHCs. Applicants should keep in mind that they may enter into clinical services contracts with other providers, such as other FQHCs, clinics or doctors, to provide some of the required services, but they should be prepared to provide a majority of the services themselves. Further, the provider must evaluate whether it (either by itself or with its collaborators) is able to satisfy the other Section 330-related organizational and operational requirements discussed earlier in this article.

"Providers who are having problems supporting themselves have a difficult time supporting those Virginians who cannot pay for their health care."

If your client is located in or serving an MUA or MUP, is able to provide the required level of comprehensive primary and preventive health care services and enabling services, and is able to satisfy other Section 330-related requirements, you should then consider engaging in a needs assessment to determine whether the proposed FQHC would be sufficiently competitive for grant dollars. The BPHC has divided the needs scoring into two categories: (1) Barriers and Access to Care and (2) Health Disparity Factors. The necessary information regarding needs scoring can be found in Attachment D of PIN 2003-01, which can be found at: <ftp://ftp.hrsa.gov/bphc/docs/2003pins/2003-01.pdf>. As a threshold matter, applicants must obtain a needs score of at least 70 to be considered for review. Similar to the FY 2003 competition, it is anticipated that competition in the FY 2004 application process will be intense. Therefore, applicants should make sure that they have highly competitive needs scores. On a practical level, in FY 2004, applicants with a needs score below 90 will most likely not be successful New Access Point applicants (based on current criteria and application experience).

If your client meets all of the above-mentioned preliminary requirements and has a highly competitive needs score, its next step would be to begin preparing a Section 330 grant application, either in support of the FQHC with which it is collaborating or by itself. As stated above, the FY 2004 PIN for New Access Points has not been released, therefore the exact requirements of the application and deadlines are not known. However, it is most likely that the FY 2004 PIN will contain many, if not most, of the same requirements as the FY 2003 PIN. Therefore, you can use PIN 2003-01 to begin to gather the necessary data for the grant application. In addition to providing all of the necessary documentation and demonstrating a highly- competitive needs score, each New Access Point grant applicant must be able to demonstrate that it would be capable of being a fully operational FQHC within *90 days* of receiving its grant; therefore it is *essential* that the applicant begin preparation as early as possible.

What about FQHC Look-Alike Status?

For those providers that are interested in becoming an FQHC, and are able to satisfy all Section 330-related

organizational and operational requirements, but are not sufficiently competitive to receive grant funding, or are unable to affiliate with an existing FQHC, there may another alternative to consider. FQHC look-alike status is another option. As discussed above, FQHC look-alike status means that DHHS has designated a provider as an FQHC based on a determination that it meets all Section 330 requirements, but the FQHC receives no Section 330 Federal funding. While FQHC look-alikes do not receive Section 330 funding, they are eligible for other FQHC-related benefits, such as enhanced reimbursement under Medicaid and Medicare and participation in the 340(B) Federal Drug Pricing program.¹⁴

Conclusion

As our health care provider clients struggle to practice medicine in today's health care environment, uninsured and underinsured Virginians lose more and more opportunities to receive health care. Providers who are having problems supporting themselves have a difficult time supporting those Virginians who cannot pay for their health care. While becoming an FQHC will not be an option for some of our clients due to their location and the needs of the populations for whom they provide care, it may be a viable option for many.

The Bush Administration's continued commitment to add more FQHCs through funding through 2006 offers a number of opportunities for health care providers in Virginia. In some cases, pursuing FQHC status may prove to be a lifeline to a health care provider that could not otherwise continue to serve its community. Securing Section 330 grants for New Access Points will ensure that there are more health care services available in Virginia to those people who need them most. For these reasons, it is important that we as advisors are aware of these opportunities and are able to explore them with our clients in the right circumstances.

¹According to a study performed by the Virginia Health Foundation in 2001, it is estimated that more than 1 million Virginians or one out of every 7 Virginians is uninsured. 22% of Virginia's uninsured are children.

²Prior to 1996, health center programs were funded under separate sections of the Public Health Service Act ("PHSA").

Since 1996, health center funding has been consolidated under Section 330. Throughout this article, the terms "FQHCs" and "health centers" will be used interchangeably to represent all Section 330 grantees (and look-alikes), regardless of the type of funding received.

³The FQHC entity, as a whole, must provide the full array of required services, as well as additional services necessary for its target population(s). However, multi-site FQHCs do not have to provide directly *every* service at *each* site, so long as the full continuum is available within the organization and accessible to *all* patients of the FQHC.

⁴Not all benefits discussed below are available to FQHC look-alike entities. For example, access to expansion grants and FTCA coverage and participation in many Federally sponsored initiatives and collaboratives are only available to Section 330 grantees.

⁵The Program Information Notice ("PIN") that discusses grant funding requirements for New Access Points in 2003 can be found at: <ftp://ftp.hrsa.gov/bphc/docs/2003pins/2003-01.pdf>. The "Questions and Answers" regarding this PIN can be found at: <ftp://ftp.hrsa.gov/bphc/docs/2003pins/2003-01qa.htm>.

⁶The PIN that discusses grant funding requirements for Expanded Medical Capacity in 2003 can be found at: <ftp://ftp.hrsa.gov/bphc/docs/2003pins/2003-02.pdf>. The "Questions and Answers" regarding this PIN can be found at <ftp://ftp.hrsa.gov/bphc/docs/2003pins/EMCqa3.pdf>.

⁷The PIN that discusses grant funding requirements for opportunities for existing health centers to expand/ improve access to mental health and substance abuse, oral health, pharmacy services, and quality care management services can be found at <ftp://ftp.hrsa.gov/bphc/docs/2003pins/2003-03.pdf>. The "Questions and Answers" regarding this PIN can be found at: <ftp://ftp.hrsa.gov/bphc/docs/2003pins/2003-03qa.pdf>.

⁸Applications for funds for Expanded Medical Capacity funds were due March 3, 2003. The BPHC intends to make its funding decisions for these funds on or before May 31, 2003.

⁹It is estimated that the initial planning process and needs assessment could take up to six months or more.

¹⁰For information on the Center for Primary Care and Rural Health, go to: <http://www.vdh.state.va.us/primcare/>

[center/index.html](#) and for information on the Virginia Primary Care Association, go to: www.vpca.com.

¹¹If the provider is located in or reasonably near an existing FQHC's service area, but prefers to establish a freestanding health center, it should first be able to demonstrate to the BPHC that there is sufficient unmet need to justify funding two grantees in the same area, as well as that it has attempted collaboration with the existing FQHC.

¹²If the provider decides to collaborate with an existing FQHC by becoming a Satellite of such entity, many of the Section 330-related requirements will be satisfied by the existing FQHC. Further, the existing FQHC, with assistance from the provider, will be responsible for preparing and submitting the grant application (and, for conducting all necessary preparatory steps).

¹³Please note that, some geographic areas may qualify for MUA or MUP designation, but have not been designated as of yet. This is a fairly complicated process and beyond the scope of this article.

¹⁴For more information on the FQHC Look-Alike Program, please refer to: http://bphc.hrsa.gov/chc/CHCInitiatives/health_center_lookalike.asp.

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The Virginia Health Quality Center: Forming Partnerships to Improve the Quality of Health Care

By Melissa Jones

Tom Patton found himself in a desperate situation. His mother, losing a battle with cancer, was living in Florida. He needed to find a nursing home for her very quickly. And it had to be located near Patton's home in Virginia. Like many consumers, Patton turned to the Yellow Pages and the telephone. The process was frustrating and unsuccessful until a nursing home administrator told him about Nursing Home Compare, a Medicare Web site that offers quality information on Medicare and/or Medicaid-certified nursing homes across the country.

Through the Web site, www.medicare.gov, Patton was able to pinpoint Virginia nursing homes with the right location that offered the care his mother needed while meeting the standards of quality Patton required.¹

The guesswork was taken out of an already emotional and difficult decision, and Patton was able to find the best care for his mother in a short period of time.

"I contacted each one [nursing home] that I was interested in, set up an interview time, went out and met with them and formed an opinion about where I wanted to have my mother taken based upon both the Medicare Web site and the interviews," said Patton.

Patton's timely success made a bigger difference than he could have imagined and he was grateful. Just 10 days after arriving in Virginia, his mother passed away.

"Had it taken a week to find the right place, I might have missed her," he said.

Patton's situation is not unlike many others who face the nursing home dilemma. Statistics show that most nursing home decisions must be made in as little as 48 hours. The Medicare Web site gave Patton the ability to find a facility and learn about the quality of care very quickly. Coupling what he found on the Web site with a visit to the nursing

home, Patton had what he needed to make an informed decision.

The Nursing Home Quality Initiative is part of the Centers for Medicare & Medicaid Services (CMS) public reporting and quality improvement projects that currently includes nursing homes, home health agencies, and will include hospitals in 2004. The Virginia Health Quality Center (VHQC), designated by CMS as the state's Quality Improvement Organization (QIO), launched the CMS initiative in Virginia last fall.

It is designed to give Virginians access to quality information about individual nursing homes in the state and across the country, via a national Web site. The VHQC is charged with informing the public that the information is available and also plays a critical role by helping nursing homes improve care for residents. It provides general assistance to the 282 Medicare and/or Medicaid-certified nursing homes in Virginia and is working individually with a select group of 35 facilities.

"This initiative is a prime example of how partnerships lead to success," said Joy Hogan Rozman, CEO of the VHQC who took the helm in 1997. "Early in the process, we made a conscious effort to work with nursing-home stakeholders across Virginia, and as a result, the group was able to focus on what is in the best interest of nursing home residents as well as the facilities themselves."

The public reporting initiatives follow a long history of Medicare beneficiary advocacy and outreach by the federal government. It was more than 30 years ago that Congress decided to create a program designed to ensure that older Americans, under the Medicare program, received timely, efficient and quality health care. The program outlined a national effort that would implement projects to continuously improve the quality of care for the Medicare population. The responsibility of this nationwide initiative fell to a network of Professional Standards Review Organizations (PSROs), who were charged with protecting Medicare beneficiaries and monitoring their quality of care, all while

safeguarding the integrity of Medicare. Later, PSROs transitioned into Peer Review Organizations (PROs), and today, they are referred to as Quality Improvement Organizations (QIOs). A QIO exists for each U.S. state and territory. As directed by the U.S. Department of Health and Human Services (HHS), PROs initially conducted case-review work to make certain that Medicare was paying for medical care that was in fact necessary.

The VHQC, then known as the Medical Society of Virginia Review Organization (MSVRO, established in 1984), followed PRO guidelines, and when Medicare shifted the main focus of the program to community based quality improvement and beneficiary education activities in addition to its case review, the VHQC followed suit. It worked more closely with all parties in the health care delivery system, partnering with hospitals, physician offices, nursing homes, home health agencies and pharmacies for quality improvement and other activities.

"This was a natural transition for the PRO program," said Rozman. "It provided the groundwork for what QIOs are today, independent organizations with health care partners across the country. Our common goal: healthier communities."

Today, CMS is charged with overseeing QIO activity. The QIO network, which

now serves as the country's infrastructure for quality improvement, performs medical case review and offers strategies and technical assistance to health care providers who care for Medicare beneficiaries. The goal is to focus on improving the quality of care for the Medicare population, with the hope that all Americans will benefit from the quality improvement efforts.

QIOs are governed by sections of Titles 11 and 18 of the Social Security Act, Part B, as amended by the Peer Review Improvement Act of 1982, and each operates under a "statement (or scope) of work," which outlines the areas of responsibility.

In the early 1990s, another shift in the federal agenda brought about an emphasis on helping providers improve overall quality of care. The Health Care Quality Improvement

"The VHQC spearheaded clinical projects in AMI, heart failure, pneumonia, stroke, breast cancer, diabetes and immunization in Virginia, as well as the Sisters for Mammograms Project, which targeted underserved African-American women in the Tidewater region of in Virginia. Other state-specific projects included providing technical assistance to home health agencies and the administration of flu and pneumococcal vaccinations to nursing homes residents."

Program (HCQIP) was born, and QIOs across the country were now working with hospitals and physicians to develop local quality improvement projects with data systems, data collection, analysis techniques and training.

By the end of the decade, the majority of clinical projects were national in scope and all QIOs, in addition to case review and participating in the Payment Error Prevention Program, were required to produce measurable statewide improvement in the areas of breast cancer, diabetes, heart failure, pneumonia and stroke and acute myocardial infarction (AMI).

The VHQC spearheaded clinical projects in AMI, heart failure, pneumonia, stroke, breast cancer, diabetes and immunization in Virginia, as well as the Sisters for Mammograms Project, which targeted underserved African-American women in the Tidewater region of in Virginia. Other state-specific projects included providing technical assistance to home health agencies and the administration of flu and pneumococcal vaccinations to nursing homes residents. CMS also awarded the VHQC several special studies including serving as the support contractor for the National Breast Cancer Initiative and Making the Case for Business Benefits of HCQIP, a study that demonstrated the economic benefits of quality improvement interventions carried out in hospitals and physician offices.

The successful results of the projects in Virginia elevated the state to the upper 25th percentile of states in quality improvement according to a study released in January of this year in the *Journal of the American Medical Association* (JAMA). Overall, the study found that doctors and hospitals across the United States have made broad improvements in the treatment of Medicare beneficiaries when it comes to major illnesses and chronic conditions. The study, conducted by CMS, compared data collected in 2001 with data collected three years ago, focusing on 22 clinical quality indicators for heart attack, heart failure, stroke, pneumonia, diabetes and breast cancer.

It demonstrated CMS' use of QIOs to provide technical assistance to hospitals and physicians by recommending tools and strategies for improving health care. According

to the study, the work conducted by QIOs over the three-year study period was associated with substantial improvement in care during this timeframe.

In addition to Virginia's national standing, statistics revealed that 17 of the 22 quality-of-care indicators in Virginia were at or above the national median in 2001, with six of the quality indicators showing improvement by at least 10 percentage points. Virginia successes include:

"We are very pleased with the quality improvement successes we have seen in Virginia," said Rozman. "While the VHQC drives the Medicare quality improvement efforts, many factors contribute to the overall improvement results. Key health-care partners, including physicians, hospitals and numerous community organizations have worked to achieve these improvements."

- a nearly 17 percent increase in patients being screened for or given the pneumonia vaccine, preventing possible readmission to the hospital for future episodes of pneumonia and its complications;
- a 16 percent increase in patients with diabetes having a biennial lipid profile to help monitor and control their disease;
- an 11 percent increase the administration of beta-blockers to heart-attack patients at discharge to prevent future heart damage;
- a more than 10 percent increase in the number of patients receiving ACE Inhibitors at discharge in the treatment of heart attack, minimizing heart damage and prolonging survival; and
- a 10 percent increase in smoking cessation counseling among patients admitted with heart attack.

"We are very pleased with the quality improvement successes we have seen in Virginia," said Rozman. "While the VHQC drives the Medicare quality improvement efforts, many factors contribute to the overall improvement results. Key health-care partners, including physicians, hospitals and numerous community organizations have worked to achieve these improvements."

The VHQC, a 501(c)(3) non-profit corporation, has clients in both the public and private sectors. Its corporate structure, as an independent entity, is important given the nature of its case review work. An independent, 19-member board of directors, made up of physicians, health care experts and other community leaders, governs the VHQC. The VHQC staff is made up of quality improvement experts,

physicians, nurses, biostatisticians and analysts, health educators and public relations professionals.

The VHQC regularly partners with Virginia's health care community to improve patient care in all health care settings, including hospitals, physician offices, nursing homes and home health agencies, and provides quality improvement assistance in a number of clinical topics to Virginia's acute-care hospitals and more than 700 physicians.

"The VHQC has a long history of Medicare advocacy and working to improve care, but the arm of quality improvement extends far beyond Virginia's older population," said Rozman. "Particularly in these strained economic times, it is important that the VHQC, as a QIO, stay on course to ensure that Medicare recipients and the general population, regardless of the clinical setting, are being cared for efficiently and effectively."

The seventh scope-of-work contract, which began in Virginia on Feb. 1, 2003, and will conclude Jan. 31, 2006, marked the sixth consecutive non-competitive CMS contract awarded to the VHQC. The contract calls for beneficiary protection projects as well as national public-reporting projects similar to the nursing home initiative.

"The Nursing Home Quality Initiative has been met with great success for the VHQC, the consumer and for the nursing homes," said Rozman. "We look forward to moving this project into new clinical settings. This fall, the VHQC plans to launch CMS' Home Health Quality Initiative in Virginia.

"As always our ultimate goal with quality improvement projects is to make health care more beneficial and sound for the consumer. As the number of aging Americans continues to grow, we want them to be healthy and productive for as long as possible. Quality health care will make that possible."

¹VHQC's web site at www.vhqc.org contains a link to nursing home information by Virginia county/city.

Melissa Jones is the director of public relations for the Virginia Health Quality Center. For more information on VHQC programs and initiatives, contact her at 804-289-5320.

Virginia Health Law Case Notes

By John C. Bilzor, Esquire
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Editor's Note and Disclaimer: In this first of what we hope to be a regular feature of the Virginia Health Lawyer, we have collected and summarized a number of court opinions issued in recent months which should be of interest to Virginia health care lawyers. My thanks to Cathleen P. Welsh, Esq., of Wharton Aldhizer & Weaver for her summary of the Clackamas case. This does not purport to be a complete or comprehensive collection. The cases are those that we noticed and thought would be of interest to our members. Similarly, the topic descriptions and summaries are subjective. We welcome your feedback regarding content, format, or anything else. Please direct comments to me at jbilzor@hnlaw.com or to Steve McCoy, Editor for 2003-04, at smccoy@williamsmullen.com. We would also like to hear from volunteers interested in preparing case notes for future issues.

UNITED STATES SUPREME COURT

Case: Clackamas Gastroenterology Associates v. Wells. No. 01-1435. April 22, 2003. 538 U.S. ____.

Topic: Americans with Disabilities Act; Shareholder Physicians as Employees

Summary: The Court held that four physician shareholders in a professional corporation could be counted as "employees" for the purpose of determining whether the professional corporation was covered by the Americans with Disabilities Act (ADA). Wells had been a bookkeeper for the medical practice and sued the practice under the ADA. The medical practice filed a motion to dismiss Wells' claim alleging that it was not covered by the ADA because it did not have a total of 15 employees, as the four physicians were shareholder/owners and not employees. The U.S. Supreme Court held that the four physicians could be counted as employees and remanded the case back to the district court to determine whether, under the newly articulated test, the four physicians should be counted.

Historically, Congress has exempted small firms and businesses from most anti-discrimination and employment

laws by setting threshold numbers of employees for the statutes to apply, e.g., Title VII (15), Americans With Disabilities Act (15), Age Discrimination in Employment Act (20), Family and Medical Leave Act (50). The Clackamas Court reaffirmed that the corporate form chosen does not dictate who is counted as an employee. Rather the answer to that question turns on a factual determination of whether the shareholder, partner or member operates independently and manages the business (an "employer"), or is subject to the company's control (an "employee"). The Court also approved of six factors advocated by the Equal Opportunity Employment Commission as being relevant to the inquiry whether a shareholder-director is an employee. The factors are: (i) whether the organization can hire or fire the individual or set the rules and regulations of the individual's work; (ii) whether and, if so, to what extent the organization supervises the individual's work; (iii) whether the individual reports to someone higher in the organization; (iv) whether and, if so, to what extent the individual is able to influence the organization; (v) whether the parties intended that the individual be an employee, as expressed in written agreements or contracts; and (vi) whether the individual shares in the profits, losses, and liabilities of the organization.

FOURTH CIRCUIT COURT OF APPEALS

Case: South Carolina Medical Association v. Thompson. No. 02-2001. April 25, 2003. 327 F.3d 346.

Topic: Constitutionality of HIPAA Regulations.

Summary: The South Carolina Medical Association brought a declaratory judgment action challenging provisions of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and regulations promulgated pursuant to HIPAA. The Court of Appeals affirmed the District Court's dismissal of the suit holding that (i) HIPAA did not impermissibly delegate the legislative function; (ii) regulations were not beyond the scope of congressional grant of authority; and (iii) neither statute nor regulations were impermissibly vague.

Case: Freilich v. Upper Chesapeake Health, Inc. No. 01-1890. December 13, 2002. 313 F.3d 205.

Topic: Termination of Staff Privileges; Constitutionality of HCQIA.

Summary: After hospital terminated physician's staff privileges, physician brought an action against the private

hospital, its board of directors, and the state and the federal government, challenging the constitutionality of the Health Care Quality Improvement Act ("HCQIA"). The Court of Appeals affirmed the District Court's dismissal of her claims, stating that the physician's "complaint is an attempt to have a Federal Court supervise what amounts to little more than a physician-hospital dispute over hospital policies and the expenditure of hospital resources." The Court stated that the legitimacy of Congress's purpose in enacting HCQIA is beyond question and that the "statute attempts to balance the chilling effect of litigation on peer review with concerns for protecting physicians improperly subjected to disciplinary actions." The Court noted that HCQIA's objective reasonable standardness is a perfectly valid guide for peer review bodies and that it "embodies the discretion that health care professionals have traditionally exercised in determining whether or not their peers meet a requisite level of professional competence." The Court held that HCQIA did not violate equal protection, was not unconstitutionally vague, and did not violate the Tenth Amendment.

UNITED STATES DISTRICT COURT – EASTERN DISTRICT OF VIRGINIA

Case: Sherman v. Jones. No. CIV.A. 02-1801-AM. April 22, 2003. Alexandria Division. ___ F.Supp.2d ___.

Topic: Constitutional Right to Privacy-HIV Status

Summary: Plaintiff, an inmate in a detention facility, alleged that a guard violated his constitutional right to privacy by revealing his HIV status in the presence of other inmates. The Court noted that the Supreme Court has identified certain "zones of privacy" subject to constitutional protection but has not identified confidential medical information as falling within a zone of privacy and has never created a broad, fundamental privacy right, leaving the matter of general individual privacy rights largely to the law of individual states. Therefore, plaintiff's claim was dismissed for failure to state a claim upon which relief could be granted.

Case: Velo v. HCA Health Services. No. 3:02CV055. November 14, 2002. Richmond Division.

Topic: Peer Review Challenge; HCQIA; Attorneys' Fees.

Summary: After a peer review investigation, hospital's

board of trustees suspended physician's privileges with regard to certain surgical procedures. Physician filed suit, alleging violations of the Sherman Antitrust Act, the Health Care Quality Improvement Act of 1986, and the Civil Rights Act of 1964. Physician also alleged various state law claims, including breach of contract and conspiracy. The District Court dismissed all of physician's federal claims, finding that the physician "cannot prove any set of facts in support of his claim that would entitle him to relief on [the federal counts]." With respect to the conspiracy claim, the Court opined that the defendant doctors involved in the peer review process in the hospital itself are not legally distinct entities. "Because they are essentially a single enterprise, the doctors involved in the peer review process and [the hospital] are entitled to intra-corporate immunity and are therefore shielded from exposure to Section One of the Sherman Act." The Court dismissed the physician's complaint against the defendants for violations of HCQIA because HCQIA does not create a private cause of action. "The HCQIA was not enacted to benefit those physicians ... that are subject to peer review."

The Court subsequently found that the defendants in this action were entitled to an award of attorneys' fees and costs pursuant to HCQIA because (1) the defendants substantially prevailed; (2) the claims against them were frivolous, unreasonable, without foundation, or filed in bad faith; and (3) they had satisfied the standards of 42 U.S.C. § 11112(a). In determining the amount of the award, the Court looked at twelve factors identified in Johnson v. Georgia Highway Express, Inc., 488 F.2d 714,717 (5th Cir. 1974) and quoted by the Fourth Circuit in Rum Creek Coal Sales, Inc. v. Caperton, 31 F.3d 169,175 (4th Cir. 1994). The factors are: time and labor expended; novelty and difficulty of questions raised; skill required to properly perform the legal services; attorney's opportunity costs in pressing the litigation; customary fee for similar cases; attorneys' expectations at the outset of litigation; time limitations imposed by client or circumstances; amount in controversy and results obtained; experience, reputation and ability of the attorneys; undesirability of the case within the legal community; nature and length of professional relationship between attorney and client; and awards in similar cases. The Court also considered the facts of the case, the degree of bad faith involved, the opposing party's ability to pay an award of attorneys' fees, and the potential deterrent effect of such an award. The Court noted that

the "plaintiff chose to cast a wide net in this case ensnaring everyone from the chief executive officer of the hospital to the supervising operating room nurse. Most of the defendants who were forced to defend themselves ... played no role in the ultimate decision to limit the plaintiff's surgical privileges. Lawsuits of this type chill the willingness of physicians to participate in the vital peer review process." The Court awarded over \$98,000 in fees plus costs.

Case: Sentara v. LeBeau. No. 2:01CV242. March 1, 2002. 188 F.Supp.2d 623.

Topic: Spousal Liability for Emergency Medical Care.

Summary: Virginia Code § 8.01-220.2, dealing with "spousal liability for emergency medical care," provides that a spouse is liable for all emergency medical care furnished to his or her spouse by a physician or a hospital, "including all follow-up in-patient care provided during the initial emergency admission to any such hospital." The hospital provided both inpatient and outpatient care to the deceased spouse over a number of months in connection with the patient's lung cancer. The hospital brought suit under the statute against the patient's estate and the patient's surviving spouse to recover charges for the patient's medical care. There was no issue as to the liability of the estate for the services performed. In interpreting the plain language of the statute, the Court found that the surviving spouse would be individually liable only for inpatient care provided during the initial emergency admission to any hospital. Under the facts of this case, the spouse was not individually liable for any of the deceased patient's hospital costs.

UNITED STATES DISTRICT COURT – WESTERN DISTRICT OF VIRGINIA

Case: McCauley v. Purdue Pharma, L.P. No. 2:01CV00080. October 1, 2002. 224 F.Supp.2d 1066.

Topic: Physician-Patient Privilege; Ex Parte Interviews with Plaintiffs' Treating Physicians.

Summary: Prescription drug users brought a products liability action against manufacturers and distributors. The defendants moved the Court for permission to conduct ex parte informal interviews with plaintiffs' treating physicians. The disposition of the motion turned on the Court's application of Virginia Code § 8.01-399, which establishes

a qualified physician-patient privilege limited to civil proceedings. The statute provides that, except at the request or with the consent of the patient or as provided in the statute, no duly licensed practitioner of the healing arts shall be required to testify in any civil action regarding information acquired in the course of attending or treating the patient in a professional capacity. The statute further provides that a lawyer shall not obtain information concerning a patient from a practitioner in connection with pending or threatened litigation without the consent of the patient, except through the normal discovery process. The defendants argued that the language in subsection B of the statute gives the Court discretion to order disclosure by the patient when the Court, in its discretion, deems it necessary to the proper administration of justice. The Court held that the unambiguous language of the statute does not allow the informal ex parte contact with the plaintiffs' treating physicians that was sought by the defendants. The Court ruled that the statute creates a limited waiver of the physician-patient privilege, but only insofar as the information is revealed through discovery or at trial.

Case: Woods v. Gliatech, Inc. No. CIV.A.7:01CV00314. August 27, 2002. 218 F.Supp.2d 802.

Topic: Medical Device; Preemption under Food, Drug, and Cosmetic Act.

Summary: Patient brought personal injury action against the developer of a medical device, alleging negligence, breach of warranty, and fraud. The developer moved to dismiss the action on the theory that it obtained premarket approval for the medical device from the FDA pursuant to the Medical Device Amendments of 1976 ("MDA") to the Federal Food, Drug, and Cosmetic Act. Although the MDA does include an express preemption provision, FDA Regulation 21 C.F.R. § 808.1 provides that "state or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the Act ..." The defendant argued that the FDA's premarket approval application process itself constitutes a specific federal requirement. The Court rejected that argument. "[C]onditional approval without more, neither provides a substantive benchmark nor implies that the FDA has endorsed the safety of the device or its manufacturing process. Conditional approval, by itself, is not a preemptive event; it is not a preemptive federal requirement. Conditional

approval leaves the gate open to claims that do not conflict with a specific federal requirement."

VIRGINIA SUPREME COURT

Case: Berner v. Mills. No. 021006. April 17, 2003

Topic: Retroactive Application of Amendments to the Virginia Birth-Related Neurological Injury Compensation Act.

Summary: Plaintiffs filed a wrongful death claim against a physician and his employer, a professional corporation, in connection with a birth-related neurological injury. The physician and the corporation asked the Circuit Court to refer the claim to the Virginia Worker's Compensation Commission (the "Commission") to determine whatever the Commission had exclusive jurisdiction to consider the claim under the Virginia Birth-Related Neurological Injury Compensation Act (the "Act"), Code §§ 38.2-5000 through -5021. The Act generally provides the sole remedy for infants who have incurred a birth-related neurological injury caused by a "participating physician" or a "participating hospital" and bars related actions against such participating physicians or participating hospitals. In January 2000, the Circuit Court referred the claim to the Commission for a determination as to jurisdiction. In March 2000, the Virginia Supreme Court decided Fruiterman v. Waziri, 259 Va. 540, 525 S.E.2d 552, in which the Court held that a professional corporation did not qualify as a "participating physician" or a "participating hospital." Based on that ruling, the Commission remanded the case to the Circuit Court, even though statutory amendments effective on April 1, 2000, expanded the definition of "participating physician" to include a professional corporation or other entity through which the physician practices. The defendants argued that the statutory amendments clarified what the law always was intended to be. The Commission ruled that the amendments did not apply retroactively. This decision was affirmed by the Virginia Court of Appeals and then by the Virginia Supreme Court based on principles of statutory construction that retroactive laws are not favored and that a statute is always construed to operate prospectively unless a contrary intent is manifest.

Case: Fuste v. Riverside Healthcare Association. January 10, 2003. 265 Va. 127, 575 S.E.2d 858.

Topic: Defamation of Physicians; Immunity Under HCQIA.

Summary: A dispute arose between the plaintiff doctors and Riverside Healthcare Association ("RHA") which resulted in both doctors terminating their employment with RHA and then opening a new medical practice. The doctors claimed that the defendant defamed them in order to harm the plaintiffs' new medical practice. The doctors alleged that certain statements made by agents and employees of RHA were defamatory--specifically that the doctors' were "unprofessional," "uncooperative," that they had "left suddenly" and "abandoned their patients," and that there were "concerns about their competence." The Circuit Court sustained the defendant's demurrer with regard to the allegations of defamation, stating that the alleged defamatory statements appeared to be "opinions by and between people involved in the healthcare field." The Virginia Supreme Court held that the alleged statements that the doctors "abandoned" their patients and that there were "concerns about their competence" prejudiced the doctors in the practice of their profession and contained "a provably false factual connotation." Therefore, the alleged statements may form the basis of a cause of action for defamation *per se*. The Court ruled that other alleged statements were expressions of opinion, did not prejudice the doctors in their professions or, taken in their plain and natural meaning, were not defamatory. With respect to the statements that the Court held could be defamatory, the defendants argued that any statements allegedly made by them during their own credentialing process or to the credentialing officials at other hospitals were privileged and therefore not actionable. The Court expressed no opinion on the issue of privilege because there was also an allegation of malice, and if proved, the presence of malice would overcome a qualified privilege. The defendants also asserted that the Health Care Quality Improvement Act of 1986 provided immunity to them in the context of the professional review action. The Court declined to decide whether any of the statutory provisions of HCQIA applied to the case, but noted that the language of the statute denied the privilege in a situation where the information is false and the person providing it knew that the information was false.

VIRGINIA COURT OF APPEALS

Case: Goad v. Virginia Board of Medicine. No. 0016-02-2. May 20, 2003.

Topic: Unprofessional Conduct; Board of Medicine; Applicable Standards of Ethics; Record on Appeal.

Summary: The Virginia Board of Medicine found a physician guilty of unprofessional conduct under former Code §§ 54.1-2914(A)(9) and 54.1-2914(A)(13) and imposed sanctions under Code § 54.1-2915(A)(3). The Circuit Court affirmed the Board's order. The Court of Appeals reversed and remanded the case, "finding the record lacks substantial evidence to support the Board's determination that [physician] was guilty of having engaged in unprofessional conduct under former Code §§ 54.1-2914(A)(9) and 54.1-2914(A)(13)." Based on reports from the Medical College of Virginia, the Board found that the physician had engaged in "inappropriate behavior toward female medical students which represented a pattern of sexual harassment under Medical College of Virginia's guidelines as well as inappropriate use of a supervisory role during clinical on-call time period." In its analysis, the Court of Appeals said that in seeking to have the Board suspend or revoke the physician's license, the burden was on the Commonwealth to establish three things: (1) the applicable standards of ethics of his branch of the healing arts; (2) the specific ethical standard he was alleged to have violated, and (3) his violation of that standard. Although the Commonwealth introduced into the record certain sections of the American Medical Association's Code of Medical Ethics and the American Psychiatric Association's Principles of Medical Ethics, the Board had not promulgated a regulation establishing any set of ethical standards as being the applicable standards under former Code § 54.1-2914(A)(9). The Court reasoned that because no evidence was presented establishing these standards of ethics by which his conduct was to be adjudicated under the applicable Code Section, "there was not substantial evidence in the record upon which the Board could reasonably find that the physician conducted his practice in a manner contrary to the standards of ethics of his branch of the healing arts." The Court further found that there was no evidence in the record demonstrating that the physician performed any act likely to deceive, defraud, or harm the public in violation of former Code §§ 54.1-2914(A)(13).

Case: Mullins v. Commonwealth. No. 2113-02-3. February 25, 2003.

Topic: Involuntary Medical Treatment; Record on Appeal

Summary: Patient-Plaintiff was involuntarily committed to a mental health facility in 1995 and has continued to reside there. In connection with the patient's development

of various physical problems, the patient's treating physician and psychiatrist sought judicial authorization to perform various diagnostic tests. The Circuit Court conducted a hearing in the patient's hospital room, found that the patient was incapable of giving knowing consent to the proposed treatment, and ordered that the treatment be administered pursuant to Virginia Code § 37.1-134.21. The statute authorizes a circuit court to order treatment "if it finds upon clear and convincing evidence that (i) the person is either incapable of making an informed decision on his own behalf or is incapable of communicating such a decision due to a physical or mental disorder and (ii) the proposed action is in the best interest of the person." Subsection (H) of the statute further provides that "the court shall not authorize a proposed course of treatment which is proven by a preponderance of the evidence to be contrary to the person's religious beliefs or basic values unless such treatment is necessary to prevent death or a serious irreversible condition." Although the plaintiff argued on appeal that there was insufficient evidence of his being incapable of making an informed decision, the Court of Appeals found there was a failure by the parties to provide an adequate record that would allow the Court to consider the argument based on sufficiency of the evidence. In a footnote the Court noted that "all parties should take care to ensure that the treatment order of the trial court and the record reflect that each of the statutory requirements has been fully met in order to provide a reviewing court with the necessary record." The plaintiff also argued that the trial court failed to take account of his "basic values," but the record did not reflect that this issue was ever raised to the trial court. The Court therefore affirmed the order of the Circuit Court.

VIRGINIA CIRCUIT COURT

Case: Riverside Hospital, Inc. v. Stroube. Williamsburg-James City County Ch. No. 13836. March 17, 2003. 2003 WL 1793084.

Topic: Denial of COPN for MRI Service.

Summary: The State Healthcare Commissioner ("Commissioner") denied Riverside Hospital's application for a Certificate of Public Need to expand its mobile MRI network to Williamsburg Crossing. At approximately the same time the Commissioner approved an application by Sentara Healthcare for the establishment of an MRI service

at Williamsburg Community Hospital. Riverside appealed the Commissioner's denial of its application for a COPN. The Circuit Court ruled that the Commissioner did not err in his decision to deny Riverside's application for a COPN because Riverside's proposal did not meet the second part of the test in 12 VAC 5-320-150, and there was ample evidence to support the Commissioner's decision to grant Sentara a COPN. The Court noted that the State Medical Facilities Plan states that applications for locations providing *hospital-based* MRI services are to be given preference. The Commissioner concluded that Sentara Healthcare's application was hospital-based, but Riverside's was not because Williamsburg Crossing was not physically attached to or adjacent to a hospital. The Court noted that 12 VAC 5-320-10 states that the criteria for being hospital-based include not only being physically attached to a hospital, but also "legally associated with... one or more hospitals." Because the Williamsburg Crossing facility is a satellite medical office building legally associated with the Riverside Regional Medical Center, the Court found that the Commissioner erred in concluding that Williamsburg Crossing was not hospital-based. Nevertheless, the Court upheld the Commissioner's ruling based on the second factor addressed by 12 VAC 5-320-150. Section D of the Regulation states that "no MRI service should be approved at a site which is within 45 minutes driving time of: (i) a COPN-approved or exempt MRI service that is not yet operational; or (ii) an existing MRI service that has performed fewer than 3,500 MRI scans or at least 3,000 MRI scans excluding those performed on behalf of the applicant during the relevant reporting period." The Court found that Riverside did not meet the threshold requirement of 3,500 scans per reporting period at a facility within 45 minutes of the proposed site.

Case: Carroll v. Cook. Loudoun County. No. 23636. September 19, 2002.

Topic: Medical Malpractice; Negligent Hiring/Retention; Negligent Supervision; Negligent Implementation of Policies and Procedures.

Summary: On defendant's motion to reconsider, the Court reversed its prior ruling and granted defendants' demurrer with respect to one of plaintiff's counts, holding that negligent supervision, negligent hiring/retention, and negligent implementation of policies, procedures, and protocols are not proper causes of action in a Virginia medical malpractice case as a matter of law.

Case: Day v. Medical Facilities of America, Inc. Salem. No. CL02-3. August 21, 2002. 59 Va. Cir. 378.

Topic: Discovery of a Medical Facility's Policies and Procedures.

Summary: In an apparent malpractice action, the plaintiff moved to compel production of the defendant medical facility's policies, procedures, protocols, guidelines, and training materials relating to the prevention, treatment, and documentation of pressure ulcers and infection. Virginia Code §8.01-581.17 provides that "the proceedings, minutes, records, and reports of any (i) medical staff committee, utilization review committee, or other committee as specified in § 8.01-581.16 and (ii) nonprofit entity that provides a centralized credentialing service, together with all communications, both oral and written, originating in or provided to such committees or entities, are privileged communications which may not be disclosed or obtained by legal discovery proceedings unless a Circuit Court, after a hearing and for a good cause arising from extraordinary circumstances being shown, orders the disclosure of such proceedings, minutes, records, reports, or communications." This Court noted a division among Virginia Circuit Courts as to whether §8.01-581.17 prevents discovery of a health facility's policies and procedures. This Court concluded that the protocols and procedures sought by the plaintiff do not fall within the scope of the term "communications," as they are not analogous to proceedings, minutes, records, or reports and thus were not protected from disclosure by legal disclosure. With respect to admissibility of such policies and procedures, this Court "follows the view of the greater number of Circuit Courts that the defendant's policies and procedures, although discoverable, are not generally admissible."

Case: Monahan v. Obici Medical Management Services, Inc. Suffolk. No. CL01-573. August 2, 2002. 59 Va. Cir. 307.

Topic: Supervision of Nurse Practitioner; Implied Physician-Patient Relationship.

Summary: Plaintiff claimed he received substandard medical treatment from a nurse practitioner. He sued the nurse practitioner and her employer and also sued a physician who never saw, treated, and/or examined the plaintiff. The plaintiff claimed that (i) there was a physician-patient relationship between them implied at law because of statutes

and regulations imposing a duty on the physician to supervise the nurse practitioner and (ii) a consensual physician-patient relationship existed between the plaintiff and the physician under the facts of the case. The physician moved to dismiss all claims against him with prejudice because he had no physician-patient relationship with the plaintiff. The plaintiff contended that there was an implied-in-law relationship because Va. Code § 54.1-2901(3) authorizes nurse practitioners to render care "under the supervision of a duly licensed physician," and the physician served as the supervising physician for the nurse practitioner. Under Virginia Board of Medicine regulations, the term "supervision" means that the physician must maintain "ultimate responsibility for the agreed-upon course of treatment and medications prescribed." 18 VAC § 90-40-10. The Court noted that under Virginia common law, a legal duty of care "arises only upon the creation of a physician-patient relationship" and that creation "springs from a consensual transaction, a contract, expressed or implied, general or special" The Court held that the enabling statutes and regulations regarding nurse practitioners do not themselves create a consensual relationship, even an implied one. To the contrary, they deal exclusively with the relationship between the nurse practitioner and the supervising physician, not the relationship between the patient and the physician.

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