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Letter from the Section Chair



Mark S. Hedberg
Chair, VBA Health Law Section
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Dear Section Members:

One of the central missions of The Virginia Bar Association is working to improve the law and the administration of justice in Virginia through active participation in the legislative process. As I write, the 2007 General Assembly Session has just concluded (the veto session was last week) and our health law legislative summary has been mailed (and emailed) to all Section members. The last event of the Section's 2007 legislative year is the Ninth Annual Health Law Legislative Update and Extravaganza, to be held on May 2, 2007, at the Richmond Omni (this is a change in venue from our usual location in the General Assembly building). The Extravaganza is a perennial favorite. Pat Devine, Chairman of our Legislative Committee, has once again assembled an excellent panel of experts to discuss the Session just ended and to look forward to 2008, and Alan Goldberg, Chairman of our CLE Committee, and Barbara Balogh, Assistant VSB Ethics Counsel, will present an ethics program entitled "Ethics: The Ten Worst Things That Can Happen to a Health Lawyer; How to Prevent Moving from Naivety to Professional Irresponsibility." I hope to see you there.

With the close of the Section's 2007 legislative year comes the start of planning for 2008. As we begin gathering ideas

for our legislative proposals, I think it is helpful to remember the VBA's legislative philosophy, which was summarized by Bill Van Buren in his President's Page in the August/September 2006 issue of the *VBA News Journal*:

The Board must approve all legislative initiatives. Our focus is on law reform that improves the administration of justice, eliminates ambiguity in the statutory scheme and enhances the overall progressiveness of our code system to improve its compatibility with federal and other state schemes. We try to avoid issues that represent the interests of a narrow business constituency or that are likely to be politically sensitive, either because they involve moral judgments, or specific economic interests. We do run the risk from time to time that not all of our members will agree with the positions we take. The Board's job is to be sure we are engaging in law reform for the right reasons as the conscience of the profession and a resource to the Virginia legislature. We serve as a check on the work of the substantive law sections to be sure that the contrary views are understood and respected and to be sure that the motivation for the change is consistent with our overall charge. Hopefully, we get that right most of the time but we look to our Board members to help us remain cognizant of other perspectives.

Typically, the Health Law Section's legislative proposals focus on the elimination of ambiguity in the Code (such as standardizing use of the federal Antikickback Law safe harbors as exceptions to Virginia's fraud and abuse laws) or improving consistency and compatibility with federal law (our latest challenge in this regard has been the HIPAA Privacy and Security Rules).

Inconsistencies, however, are not always purely statutory. Two recent decisions of the Supreme Court of Virginia in the health law arena interpret statutes in a way that raises significant issues for health care lawyers throughout the Commonwealth and these interpretations are likely to be addressed through legislation in the 2008 Session. The first case involved the discoverability of provider incident reports. Prior to the Supreme Court's decision last November in *Riverside Hosp. v. Johnson*, 272 Va. 518, 636 S.E.2d 416 (2006), it was generally understood that the Va. Code § 8.01-581.17.B

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applied to any document provided to a medical staff or other committee described in Va. Code § 8.01-581.16 (that is, after all, what the statute says), and that as a result such documents could not be disclosed, or obtained through discovery, unless a circuit court ordered the disclosure after a hearing and for good cause arising from extraordinary circumstances having been shown.

In *Riverside*, the question before the court was whether an incident report pertaining to the fall of a nursing home patient was privileged as a communication provided to a peer review or quality care committee. 272 Va. at 424, 636 S.E.2d at 532. Although the Court noted that it was unclear from the record whether or not the incident report in question had been given to a peer review or quality care committee, 272 Va. at 423 n.7, 636 S.E.2d at 531 n.7, the Court declined to rule on this basis and considered the discoverability of incident reports generally. According to the Court, a "literal application of the phrase 'all communications, both oral and written, . . . provided to such committees' would impress the privilege on every document and every statement made available to a committee or entity identified in the statute. Such an application would allow a health care facility to immunize from disclosure every statement or document maintained by the facility simply by insuring that such statement or document was provided or available to peer or quality review committee." 272 Va. at 424, 636 S.E.2d at 532. Although acknowledging that "The obvious legislative intent [of the statute] is to promote open and frank discussion during the peer review process among health care providers in furtherance of the overall goal of improvement of the health care system," the Court held:

The deliberative process involving evaluation of patient safety conditions and the design of initiatives to improve the health care system both necessarily begin with factual information of patient care incidents occurring within the health care facility. The use of this factual information in some way in the peer review or quality care committee process alone is insufficient to automatically cloak such information with the protection of non-disclosure. Factual patient care incident information that does not contain or reflect any committee discussion or action by the committee reviewing the information is not the type of information that must "necessarily be confidential" in order to allow participation in the peer or quality assurance review process. Rather such information is the type, contemplated by Subsection (C) of Code § 8.01-581.17, which the General Assembly has specifically instructed should not be brought within the scope of those items entitled to the privilege under any other part of the section.

272 Va. at 424, 636 S.E.2d at 532. Thus, the *Riverside* decision not only removes incident reports from the scope of the peer review privilege in Virginia, it calls into question whether any facts disclosed to a peer review committee during its investigation will be privileged.

The second case, *Parikh v. Family Care Center*, ___ Va. ___, 641 S.E.2d 98, No. 060934 (Sup. Ct. Va. Mar. 2, 2007), involved the enforceability of what the Court described as a "covenant not to compete" in a physician employment agreement. At the time Dr. Parikh terminated his employment with the Family Health Care Center, the Center was a Virginia corporation (not a professional corporation). Dr. Parikh was then employed by a group less than a mile away from the Center and the Center sought to enforce the noncompete in Dr. Parikh's employment agreement, which required him to pay the Center \$10,000 per month if he was employed to practice his specialty within a 20-mile radius of the Center. Dr. Parikh argued that the noncompete was unenforceable because the Center could not engage in the practice of medicine and therefore did not have a legitimate business interest in enforcing the covenant not to compete.

The Court agreed with Dr. Parikh and declined to enforce the contract. The opinion addresses the statutes in Title 54.1 of the Virginia Code which prohibit the practice of medicine without a license and the statutes in Title 13.1 of the Code which address the way in which professional corporations and non-professional corporations may render professional services in Virginia. The opinion seems to turn on a distinction between the practice of medicine and the rendering of professional services through employed or contracted physicians (although one could argue that having assumed that the Center could lawfully employ Dr. Parikh it was incongruous at best for the Court to then conclude that the Center has no legitimate interest in enforcing its noncompete against its former employee).

The issues raised by these cases may well be contentious when they come before the General Assembly next year. If you have any views on these, or any other potential legislative subject, please let me (mhedberg@hunton.com) or Pat Devine (pdevine@williamsmullen.com) know.

* * * * *

In closing, let me take a moment to extend a heartfelt thank you to Jon Joseph, who has just concluded his second term as our Chairman. Under Jon's leadership, the Section sponsored numerous excellent CLE programs, maintained an active legislative agenda and enhanced communications with the Section's members (through efforts such as this newsletter). Luckily, the Council will continue to have the benefit of his thoughts as Immediate Past Chair.

Sincerely yours,

Mark

Mark S. Hedberg
Chair, VBA Health Law Section

Negotiating Software Contracts



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Health lawyers are increasingly becoming involved in transactions that require a basic knowledge of the law of intellectual property, now that electronic health records, ePrescribing, and other computer technology features of health care are receiving more attention and more funding. The licensing of software by health care providers and payors is now a regular part of health care payment, delivery, and operations, and the contract terms can be challenging and troublesome for the unschooled. The purpose of this article is to provide a basic understanding of what clients licensing software (end users) will need in order to be protected and provides an overview of the issues that distinguish software licensing contracts from most other commercial agreements; it is not a listing of every legal issue presented by a typical license.

End users need to be assured that their contract protects them if the software fails to live up to the software vendors' (licensors) promises, and end users often ask their attorneys to "Keep us safe." Early intervention in the licensing process usually will reaffirm the validity of the old maxim about an ounce of prevention being worth a pound of cure. When the end user is committed to a software product, it may be impossible to cure a significant defect. Using a careful contracting process enables the end user to prevent many of the difficulties that can cause significant difficulties.

If you are fortunate enough to be consulted before an end user is committed to a particular software application, consider making the following recommendations. First, encourage an evaluation of the proposed licensor's references. The best contract in the world only mitigates a bad situation if the licensor is not reputable. Don't rely only on references provided by the licensor. User groups and other industry groups can provide excellent independent sources of information. In addition you may want to run a credit check.

Second, tell the end user to make clear to all potential licensors that the successful vendor will agree that the end user will not pay a significant portion of the license fee (at least 20 percent) until after the software application or system has been installed on the end user's system and tested with live data, subject to proper privacy and security features being employed in order to assure consistency with HIPAA Administrative Simplification subtitle transactions and data code sets, and privacy and security rules and other applicable federal and state health care laws. This is particularly important if the agreement requires any custom software development work. Even if you don't see the contract until the end user is ready to sign the agreement, try to make this change. It is the single most effective revision you can offer in order to provide protection against flawed performance.

Third, the end user will never again have as much leverage as will exist before signing the agreement. Consider negotiating concessions from the licensor such as guaranteeing prices on acquiring additional software modules, capping increases on future licensing and

maintenance fees, and representing that the licensor will continue to support the software for at least five or more years, or will pay for the end user to migrate to a new product.

If the licensor has included a maintenance agreement in the same document as the license agreement, you will want to separate the two. Negotiate the maintenance agreement before the end user is committed to the license agreement, and try to give the end user the ability to cancel maintenance services without affecting the viability of the license agreement.

The length of the warranties is often tied to price and warranty periods typically last from 60 days to one year. Some of the important warranties to look for from a vendor are as follows:

- i. The licensor has valid right, title and authority to grant the license. This is increasingly important with the frequent incorporation of third party software.
- ii. The system as a whole will operate as advertised. This is especially important in a situation in which certain modules come on line at different times, and each is accepted as they are brought up. If each module works well independently, but they don't work together, a system warranty should protect the end user.
- iii. The software will meet certain performance standards:
 - a) *Objective and measurable standards* – if the software fails to meet a standard, and that failure is repeatable, the software fails.
 - b) *Subjective test* – rather than rely on stating all the parameters of each objective measurement, some end users prefer to have the ability to try software with their data for a 30-60 day trial period.
- iv. Services will be performed in a professional and workmanlike and a "commercially reasonable" manner.
- v. The software documentation accurately describes the functional and operational characteristics of the software. The end user's technical experts should review and analyze the documentation to make sure that it clearly and definitively identifies the software's capabilities. Even if the agreement guarantees that the software will perform in accordance with the published specifications, this warranty will not be helpful if the published specifications are vague.
- vi. The software does not infringe any third party rights. Licensors sometimes argue that they can't search all patents and copyrights to make sure there is no infringement, and

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so they resist making this representation. Your fallback position is to make sure the licensor indemnifies the end user for any claims brought by third party intellectual property owners.

It is helpful to have a right of setoff in the agreement, so the end user can withhold payment (often this is the only leverage an end user has) to try to compel the licensor to fix a flaw or to respond appropriately to an issue raised by the end user. Without the right of set off, the licensor may be able to terminate the software license for failure to pay.

Software engineers write software in "source code" (no matter what programming language is used) and the code that computers read is referred to as "object code." Usually the end user only acquires the right to use and access the object code. The licensor closely guards the source code because it provides "the keys to the licensor's kingdom." This can create a challenge for the end user if the licensor ceases doing business, because the end user needs to maintain the software to keep it compatible with changing technology. To protect against this situation, licensors sometimes place their source code in escrow with a third party software escrow holder that receives updates to the source code from the licensor as it continues to change, and only releases the code to the end user if the licensor ceases doing business or otherwise can no longer fulfill its maintenance obligations. There are businesses that specialize in this service. From time to time attorneys are asked to hold source code in escrow, but I recommend against this.

Carefully review all limitation of liability provisions. It is accepted that a software company cannot be expected to be liable for all the potential damages that may arise if the

software malfunctions or fails to function. Licensors sometimes limit their exposure to a specific dollar (liquidated damages) amount or to the amount of revenue received by the licensor in a certain period of time. Limitations of liability should not apply to an intellectual property indemnity, breaches of confidentiality, or the licensor's gross negligence, willful misconduct, intentional acts, or to circumstances involving a false or misleading warranty or representation, or a violation of law.

Just because a company hires a consultant to write software code doesn't mean the company will own the copyright for the code. The copyright in custom developed software is owned by the individuals who write the code (or their employer). Many contracts refer to this as "a work for hire." "Work for hire" is a term of art in copyright, and has a much narrower definition than you would expect from the plain meaning of the words. To own the copyright in code written by a consultant, the end user needs a written assignment transferring the copyright rights. Even if a developer is willing to transfer the copyright for the custom code, he or she usually will not transfer exclusive rights in the parts of the code used for routine purposes (e.g. to tell the computer to refresh the screen), but this code is often included within the custom developed software. Typically both sides of the licensing transaction can be accommodated by having the developer transfer the copyright for the custom code and grant an irrevocable license to the end user covering the non-unique sets of code.

To summarize, the three most important points to remember are: 1) take full advantage of the increased leverage the end user has before the license agreement is signed, 2) critically examine the licensor's references, and 3) tie at least 20 percent of the license fee to the software successfully passing a well defined acceptance test.

In the Public Interest: Nine Points to Consider in Licensing University Technology



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Introduction and background

Eleven U.S. universities that are successfully engaged in commercializing their inventions recently issued a document, entitled "In the Public Interest: Nine Points to Consider in Licensing University Technology (referred to hereinafter as "the White Paper"), setting forth nine principles regarding how universities may reconcile their goals to realize profit from patent licensing, and to act in the public's best interest.¹ The initiative grew out of a meeting held at Stanford University, in the summer of 2006, with research officers, licensing directors and a representative from the Association of American Medical Colleges, to discuss important societal,

policy, legislative and other issues in university technology transfer.²

It is appropriate that universities play a major role in establishing a more equitable patent licensing system, because universities have always been important participants in the creation and invention of intellectual property. Health lawyers should have a general understanding of these principles, because the increasing importance of patents and licensing in health care law and transactions generally, and life sciences law and transactions specifically, is unlikely to abate. Although not a contract legally enforceable against

the universities or a government regulatory mandate, nevertheless the White Paper provides a worthy recitation of appropriate goals for organizations that are viewed as existing to benefit the public interest.

The university is the birthplace of the biotechnology industry, and continues to be the source of much of the basic new technology that fuels the biotechnology industry. For example, the Cohen-Boyer patents for gene-splicing and biologically functional molecular chimeras, granted to Stanford University and the University of California, have provided substantial benefits to the public. University inventions also include the anticancer drug Platinol which was developed at Michigan State University and licensed to Bristol-Myers, and the Atomic Force Microscope and magnetic resonance imaging (MRI) invented by researchers at the University of California.³

Universities are criticized by some for using patents in a way that inhibits, or could inhibit, the distribution of medicines to developing countries at accessible costs. For example, universities often grant exclusive licenses to first-world pharmaceutical companies in order to provide the incentive for these companies to invest in developing the products. However, by insisting upon enforcing these patents in developing countries, the pharmaceutical companies could prevent local companies from producing and selling the drugs at affordable prices, which prevents poor people in developing countries from being treated with life-saving drugs.⁴

The genesis of the White Paper is the need to provide clear guidance to universities regarding university technology transfer and licensing best practices.

The White Paper

The White Paper addresses the following nine concerns, each of which will be discussed below: (1) Reservation of rights to practice licensed inventions; (2) Exclusivity of licenses; (3) Licensing of future improvements; (4) Conflicts of interest; (5) Access to research tools; (6) Enforcement action; (7) Export Regulations; (8) Licensing to "patent aggregators"; and (9) Protections in licenses for neglected patient populations and for developing countries.

1. Reservation of rights to practice licensed inventions

The goal of preserving the ability of all universities to continue to perform research is of paramount importance, since the *raison d'être* of a university is to engage researchers and teachers for the purpose of disseminating knowledge. As the White Paper notes, clear articulation of the scope of reserved rights is critical.

Valid concerns are raised in the Appendix to the White Paper regarding the definition of the term "non-commercial uses" in reserved/retained rights clauses. Two recent decisions by the Court of Appeals for the Federal Circuit: *Integra Life Sciences I Ltd. v. Merck KGaA*,⁵ ("*Integra*"), and *John M.J. Madey v. Duke University*,⁶ ("*Madey*") address the experimental use exception, one of the exceptions to the rule that use of a patented invention without authorization by the patentee is an unlawful infringement.⁷

The common law experimental use exception is a judicially-created exception for certain activities that do not adversely impact the pecuniary interests of the patentee, and have no more than a *de minimis* impact on the patentee. The above-mentioned decisions support the interpretation that regardless of whether a particular institution is engaged

in an endeavor for commercial gain, if an action is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the action will not qualify for the very narrow and strictly limited experimental use defense.

While the experimental use exception leaves room for the patentee to reserve rights for itself, it is questionable whether, in light of *Integra*⁸ and *Madey*,⁹ the reservation of rights by a patentee for "other non-profit academic research institutions" who are not part of a known, defined group, and not parties to a formal license agreement, is a valid reservation. It is submitted that this method of granting rights to other parties via the reserved/retained rights clause could create confusion and uncertainty *vis-a-vis* the party with whom the university has entered into a formal licensing arrangement, and also, may give rise to claims of patent infringement as contemplated in *Integra*¹⁰ and *Madey*.¹¹

2. Exclusivity of licenses

The White Paper cautions that universities should be mindful of the impact of granting overly broad exclusive rights and should strive to grant just those rights necessary to encourage development of a technology. The White Paper further encourages the use of the following strategies where an exclusive license is warranted:

1. Developmental/Performance milestones; and
2. Compulsory sublicensing.

Milestones should be meaningful and provide the appropriate balance of incentives, rewards and penalties. "Milestone clauses" should be carefully drafted, and require detailed preparations. Their drafting and negotiation require a sound understanding of the processes related to developing and marketing a product, realistic forecasting of product potential, persistence in quantitative forecasting and in putting together a master plan for the entire product roll-out, and a mission-driven mindset. Additionally, it is useful to spell out the level and condition of fines (monetary or otherwise) to be paid when a licensing partner does not fulfill obligations, including a mechanism to prevent prolonged periods of dispute. Most "milestone clauses" generally cover: pricing to the public sector; territory; regulatory work and time to market; and specification of penalties and fines levied against the licensee if these milestones are not reached.¹²

Additionally, requests for exclusivity should be linked with specific milestones such as:

- i. The volume of sales reached in certain markets after a certain time period from launch or from signing the agreement;
- ii. The level of market share reached against competition;
- iii. The level of market share established in a new market segment, measured against the total product potential; and
- iv. The latest product launch date into a market that will secure product/technology exclusivity for the company in general, for a selected territory.¹³

Considering the sample milestone clauses in the Appendix to the White Paper in light of the points mentioned above, it

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Nine Points to Consider

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is submitted that they are, generally, in keeping with best practice milestone strategies. However, as discussed above, in each case, milestone clauses require intensive preparations and careful drafting.

3. Licensing of future improvements

The White Paper advises that exclusive licensees should not automatically receive rights to improvement or follow-on inventions, because such rights could inappropriately bind a faculty member's research program to a particular company. This is a valid consideration, and it is submitted that in the rare instance in which a licensee is granted rights to improvement patents, those should be limited using the same strategies discussed above, to wit, (1) compulsory sublicensing; and (2) developmental/performance milestones.

4. Conflicts of interest

As the White Paper notes, university technology transfer officers should be sensitive to the management of conflicts of interest. The types of conflicts that universities need to be mindful of include the following:

- i. Conflicts between the goals of maximizing royalty income and promoting publication, between commitments to fostering spinout companies and to preserving university resources, or between strong intellectual property ownership policies or indirect cost rates and attempts to bring in more research support from industry;
- ii. Conflicts of interest that may arise when university administrations are called upon to make exceptions to long-standing policies in order to bring in a big program;
- iii. Conflicts arising from time commitments, such as between time spent in university teaching and research and time spent with the spinout company; and
- iv. Conflicts as regards the use of students on company projects.¹⁴

Putting in place written policies that are well thought out and consistently applied can avoid many conflicts of interest. Universities should establish a clearly defined chain of command for ruling on most of these conflicts issues.¹⁵

5. Access to research tools

The White Paper notes that universities, in keeping with their missions, should make research tools as broadly available as possible. It is submitted that in licensing research tools, it is useful to bear in mind the concerns raised above in Section 2 regarding license exclusivity.

6. Enforcement Action

Universities should be mindful of their mission to promote technology development for the benefit of society, and, as much as possible, should avoid litigation. This is in keeping with current practice as regards intellectual property disputes, which are very often resolved by resort to various means of alternative dispute resolution (for example, mediation and/or arbitration).

7. Export regulations

University technology transfer offices are also advised to

be mindful of export regulations. It is submitted that technology transfer offices should be knowledgeable not only about export regulations, but also all international intellectual property conventions, especially the World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement).

8. Patent Aggregators

The White Paper provides advice with respect to dealing with patent aggregators that: (1) assemble portfolios of patents related to a particular technology; and (2) acquire rights that cut across one or more technological fields with no real intention of commercializing the technologies ('patent trolls'). The White Paper cautions against working with 'patent trolls', who unlike other patent aggregators who add value through technology-appropriate bundling of intellectual property rights, extract payment without having contributed to any enhancement of the licensed technology, and rely on threats of infringement litigation to generate revenue. This advice is certainly helpful, as a university may be unaware of the ways in which patent licensees may, whether intentionally or not, cause the university to appear to be acting contrary to the best interest of the public.

9. Neglected populations and developing countries

The White Paper speaks to the duty of universities to engage in responsible licensing, which includes considering the needs of people in developing countries and neglected patient populations. Some strategies for achieving this goal include:

- Control over pricing in developing countries: prices can be set at a small percentage of cost;
- Requirement of delivery of products for developing countries: a university may require that a company begin the testing and distribution of products in developing countries simultaneously, or at least within a very short time frame after, introducing them in first-world countries; and
- Where a drug or vaccine has a large first world market, prohibiting the patent from being filed in developing countries.¹⁶

Conclusion

The White Paper is a commendable document and a good first step towards the creation of a more equitable patent licensing regime. It is hoped that the suggestions put forward in the White Paper, will be adhered to by universities and other academic institutions, so that, particularly in health care and life sciences, the public interest will be better served.

NOTES

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1. The 11 universities that signed on to the White Paper are California Institute of Technology, Cornell University, Harvard University,

Massachusetts Institute of Technology, Stanford University, University of California, University of Illinois, Chicago, University of Illinois, Urbana-Champaign, University of Washington, Wisconsin Alumni Research Foundation, Yale University. The Association of American Medical Colleges also signed the White Paper. See The Chronicle of Higher Education, "Leaders in Licensing of Academic Inventions Suggest Guidance on Practices and Ethical Concerns" at <http://chronicle.com/daily/2007/03/2007030705n.htm>.

2. See, "In the Public Interest: Nine Points to Consider in Licensing University Technology" at <http://news-service.stanford.edu/news/2007/march7/gifs/whitepaper.pdf>.

3. Kenneth Sutherland Dueker, "Biobusiness on Campus: Commercialization of University-Developed Biomedical Technologies" 52 Food and Drug L.J. 453(1997).

4. Lita Nelsen, "Case Study: The Role of University Technology Transfer Operations in Assuring Access to Medicines and Vaccines in Developing Countries" 3 Yale J. Healthy Policy Law & Ethics 301 (2003)

5. 331 F.3d 860 (Fed.Cir.2003).

6. 307 F.3d 1351 (Fed.Cir.2002).

7. The other exception is a statutory exception under 35 U.S.C. 271(e)(1), which provides that "it shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention...solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."

8. See *supra* note 5.

9. See *supra* note 6.

10. See *supra* note 5.

11. See *supra* note 6.

12. See, MIHR and PIPRA, INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES (2006).

13. See *id.*

14. See *supra* note 12.

15. See *supra* note 12.

16. See *supra* note 4.

Second Annual Virginia Advance Directives Day

Virginia's lawyers and health care providers once again collaborate to educate the public about advance health care planning and to lead by example



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Project Committee
McGuireWoods LLP, Richmond

April 17, 2007, was the Second Annual Advance Directives Day, a statewide event designed to highlight the importance of advance health care decision-making for all adults, regardless of age or current health status. On this day, throughout Virginia, free information and presentations were available to help people execute advance directives (designating a health care decision-making agent and/or creating a "living will").

For the second year in a row, every acute care hospital in Virginia participated in Virginia Advance Directives Day. Therefore, all Virginians were encouraged to visit local hospitals on April 17 to obtain free Advance Directives forms and information on how to name an agent for health care decisions and/or create a living will.

Along with Virginia's hospitals, numerous nursing homes, assisted living facilities, hospices, continuing care retirement communities, adult day centers, and physicians engaged in a variety of activities to encourage people to make their health care decisions known.

The list of participating facilities can be found at www.vsb.org/sections/hl/advancedirectivesday2007.html.

The Virginia Advance Directives Day webpage also contains free forms (including a large print form), educational information (including a Spanish information document), and a variety of links (including links for organizations that offer forms for people in other states).

Virginia Advance Directives Day was created by members of the Health Law Sections of The Virginia Bar Association

and the Virginia State Bar to educate the public about the importance of advance care planning and to increase the number of Virginians who make their health care wishes known in writing. This year's Advance Directives Day included 193 participating facilities, was reported upon in at least 30 newspapers and several television and radio stations, and touched the lives of well over 6,000 Virginians.

Affirming the importance of this initiative, Governor Timothy M. Kaine officially recognized April 17, 2007, as (the second annual) Virginia Advance Directives Day. Last year's Virginia Advance Directives Day included 197 participating facilities, was reported upon in at least 30 newspapers, two television stations, and a radio station, and touched the lives of at least 4,600 Virginians. Furthermore, a National Advance Directives Day initiative is underway, and Virginia's extraordinary experience is serving as a model for the nation.

Throughout Virginia, lawyers participated in this event by providing information to their clients and/or by making volunteer presentations at participating facilities. Beyond this, because this topic is relevant to everyone, the entire Virginia legal community was encouraged to participate in the event through this year's "Lead by Example" push. Specifically, all Virginia attorneys should be sure that they have considered their own health care wishes and formalized

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Virginia Advance Directives Day

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them in a written advance directive. Lawyers may also be interested in the various educational materials contained on the provider's webpage: www.vsb.org/sections/hl/advancedirectivesday2007_2.html.

This event is the result of an extraordinary collaboration of The Virginia Bar Association Health Law Section, the Health Law Section of the Virginia State Bar, the Senior

Lawyers Conference of the Virginia State Bar, the Trusts and Estates Section of the Virginia State Bar, the Virginia Hospital & Healthcare Association, the Virginia Health Care Association, the Virginia Association of Nonprofit Homes for the Aging, the Virginia Association for Hospices, the Virginia Association of Free Clinics, the Virginia Department for the Aging, the Virginia Nurses Association, the Medical Society of Virginia, the Richmond Academy of Medicine, and the Virginia Adult Day Services Association.

From the Editor's Pen

Our second *Health Law News* provides a good example of how the practice of health law keeps changing. Today more than ever, Virginia health lawyers have to know and understand how judicial decisions and legislative initiatives can and do alter the way in which clients plan and implement the delivery of and payment for health care, and new areas of health law focus are emerging as well.

Our Chair, Mark Hedberg, brings us up to date regarding several new court decisions that relate to incident reports and privilege, and to a covenant not to compete. Privacy issues, and what constitutes the practice of medicine, continue to create challenges, and these decisions reaffirm the need to maintain a current knowledge of developments in these important areas of health law.

Pat Devine and Harold Han provide us with a timely update of legislative actions in the State Medical Facilities Plan (SMFP) and Certificate of Public Need (COPN) areas and we will have to remain alert to possible reintroduction of some of the bills that were not signed into law, even as we learn all about HB2546 that was signed into law. In addition to our need maintain our knowledge of health facilities law, health lawyers have to learn more about how the law of intellectual property, including patents and licenses, affects health care.

Tara Leevy provides us with an analysis of a uniquely informative and helpful publication resulting from a recent collaboration by universities regarding the successful commercialization of inventions relating to health care and benefiting the public interest in biotechnology including genetics, pharmaceuticals, and magnetic resonance imaging. The Nine Points included in the recently published White Paper, and the sample clauses contained in the Appendix, are helpful aspirational materials that will complement a busy health lawyer's need to gain insight into how to counsel physicians involved in inventions and patents and the educational institutions employing physicians and others for the development of new treatments.

Because so much is happening in the area of health care and information technology, many more health lawyers are becoming involved in software licensing involving, inter alia, electronic health records and payment systems. Recognizing this development, Ian Titley provides a basic foundation of learning for how to endeavor to protect the licensee of a software application.



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As Ian indicates, there are some features of a license that can significantly support corrective action being required in the event of disagreement, but only if those features are reflected in clauses in the license agreement.

Recognizing human mortality remains an area of stress, but having an advance health care decision-making document executed can avoid costly and tragic consequences when time is short and challenges are great. Nathan Kottkamp provides us with a description of the April 17, 2007, Second Annual Advance Directives Day, when the importance of having an advance directive was the subject of a statewide event involving a multitude of health care providers and Virginia lawyers acting in the public interest and supporting the "Lead by Example" push.

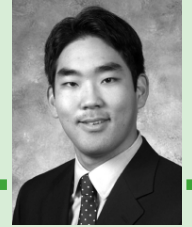
We hope that you find the *Health Law News* to be an informative addition to your readings in the law. Please let us know if you would like to contribute an article to our quarterly Health Law Section periodical. We thank the contributors to this edition and to Caroline Bolte Cardwell, Director of Communications for The Virginia Bar Association, for being so very helpful in enabling us to publish an electronic newsletter worthy of the Health Law Section of The Virginia Bar Association, we express our warm appreciation. Note also our new website feature, "Member Legal Updates," where we post summaries of new developments in health law.

Because my Communications Committee responsibilities are now at an end, I would like to express my personal appreciation to the contributors to our first and second editions of our *Health Law News* for your commitment to the educational mission of the Health Law Section, and to my colleagues in the Health Law Section for permitting me to enjoy the delight of seeking and editing the fine works we are privileged to publish for you.

Recent SMFP and Legislative Developments in Virginia's Certificate of Public Need Law



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I. Introduction.

Over the last year, a number of developments have occurred which could significantly impact Virginia's certificate of public need (COPN) regulatory landscape. During the 2007 Session of the Virginia General Assembly, several COPN bills were considered, including one introduced by members of the special House of Delegates COPN Task Force. These bills ranged from complete deregulation of the COPN program to attempts to streamline the COPN application review process. Also, after over four years of studies, revisions and meetings, the Board of Health of the Virginia Department of Health (Board) approved a draft of the revised State Medical Facilities Plan (SMFP) on February 2, 2007. This article will provide a brief overview of the key 2007 Session COPN bills and an update on the revisions to the SMFP.

II. COPN Legislation.

A. COPN Task Force.

The special House of Delegates COPN Task Force (Task Force) was formed in 2006 to (i) review the past Joint Commission on Health Care COPN studies, the 2004 Federal Trade Commission/Department of Justice Report on Certificate of Need, and relevant information on COPN-style programs in other states, (ii) examine the role of the regional health service agencies in the COPN process, and (iii) receive input from interested stakeholders as to the need for changes in Virginia's COPN law and the regulatory process. The Task Force met four times between September 2006 and December 2006. The meetings primarily focused on ways to revise and streamline the COPN process from the initial application stage to the final decision by the Commissioner of the Department of Health (Commissioner).

In addition to representatives of the Virginia Department of Health (Department), the Task Force meetings were attended by a variety of interested organizations, including representatives of the Medical Society of Virginia, Virginia Hospital & Healthcare Association, Virginia Association of Regional Health Planning Agencies, the Virginia Joint Commission on Health Care, the Virginia Orthopaedic Society, and the Virginia Health Care Association. Furthermore, the Task Force asked experts who were knowledgeable regarding COPN and industry friends to speak about issues as strategic health care trends and the impact of indigent care on hospital finances.

The Task Force and the participants seemed to be in agreement that changes need to be made to improve the COPN process and program, but the Task Force did not reach a consensus on the types or breadth of such changes. The Task Force's meetings, however, did spark much needed debate and dialogue among the industry participants regarding the need for revisions to the COPN program. As a result, a number of COPN bills were introduced in the 2007 Session, including those of Task Force members John M. O'Bannon, III (R-House District 73), Harry R. Purkey (R-House District 82) and Clarke N. Hogan (R-House District 60).

B. COPN Bills.

At least eight COPN bills related to Virginia's COPN law and regulations were introduced during the 2007 Session.¹ Several COPN bills were directly aimed at streamlining the COPN process. These bills included Delegate O'Bannon's HB 2155, which would:

- (i) eliminate regional health planning agencies from the COPN review process;
- (ii) eliminate all equipment valued at \$500,000 or less from the COPN review process;
- (iii) increase the capital expenditure review threshold from \$5 million to \$15 million or more;
- (iv) increase the number of facilities and services for which the Commissioner is authorized to issue COPNs through the "request for applications" process to include radiation therapy services, stereotactic radiosurgery services, neonatal special care services, obstetrical services, medical rehab services, psychiatric services, and long-term care and acute care hospitals;
- (v) create a requirement for holders of a COPN to report (a) patient volumes, (b) gross patient revenues, (c) net patient revenues, (d) charity care volume and (e) gross charity care expenditures; and
- (vi) require an incomplete application to be refiled in the next review batch cycle.

Delegate Purkey introduced three bills (HB 2274, HB 2276, and HB 2277) designed to overhaul and shorten the COPN process. HB 2274 would have repealed the COPN program

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in a three-phase, three year plan. Phase I of deregulation, to be completed by July 1, 2008, would have eliminated from COPN review all CT scanning, lithotripsy, MRI, MSI, PET and all nuclear medicine imaging services. Phase II of deregulation, to be completed by July 1, 2009, would have eliminated cardiac catheterization, gamma knife surgery and radiation therapy. Phase III of deregulation, the final phase to be completed by July 1, 2010, would have eliminated, among other things, ASCs, nursing home services, and extended care and skilled nursing facility services from the COPN process. In contrast to a complete repeal of the COPN program, HB 2277 was designed to streamline the COPN review by completely eliminating the regional planning agencies from the process.

Delegate Purkey's third bill, HB 2276, would have, among other things, (i) reduced the COPN application fee from a current maximum of \$20,000 to \$10,000 for contested applications and \$5,000 for uncontested applications; (ii) required a COPN application to be no more than a total of 20 pages; (iii) reduced the current 190-calendar-day review period to 60 days for uncontested applications and 90 days for contested applications; and (iv) required members of the regional health planning agency boards to comply with Sections 2.2-3112 and 2.2-3114 of the State and Local Government Conflicts of Interests Act.

C. Final Legislation.

The majority of the COPN bills did not reach the Governor's desk. Delegate O'Bannon requested that HB 2155 be stricken from the docket after the bill was amended by the House Health, Welfare and Institutions Committee to remove a key requirement eliminating from COPN review all equipment valued at \$500,000 or less. HB 2274 and HB 2277 were also stricken from the docket, and HB 2276 was defeated in the House Health, Welfare and Institutions Committee.

One COPN bill was signed into law on March 19, 2007. Delegate Hogan's bill, HB 2546, makes two seemingly minor, but overall very important, changes to the COPN review process. First, HB 2546 increases the threshold for defining a capital expenditure triggering COPN review (those not already defined as a "project" under COPN law and regulations) from \$5 million to \$15 million. Second, the Commissioner may now approve a significant change in cost for an approved project that exceeds the authorized capital expenditure by more than 20 percent, if the cost increases are reasonable and necessary and do not result from any material expansion of the project.

These changes will have positive practical ramifications. First, hospitals and other providers will now be able to initiate expenditures of less than \$15 million for programs not otherwise defined as a project by COPN law, such as minor facility expansions, general physical plan renovations and infrastructure upgrades, without the need for an application and COPN review. Second, prior to HB 2546, the Commissioner could not approve any significant change in an application that resulted in an increase in the authorized capital expenditure by more than 20 percent. If such a change had occurred, the applicant would be required to apply for a

new COPN. Now, the Commissioner has the discretionary authority to approve, without the need for a new application by the applicant, certain significant changes resulting from a 20 percent increase in capital expenditures. This should save both the applicant and the Commonwealth time and money by eliminating the need for restarting the entire COPN review process with a new application, except in when the cost increases are not reasonable and necessary and result from a material expansion of the project.

III. State Medical Facilities Plan Update.

Health care providers and practitioners should also be aware that additional changes to the COPN program are on the horizon. The Board, on February 2, 2007, finally approved the draft of the revised SMFP for an additional comment period. The SMFP is promulgated by the Center for Quality Health Care Services and Consumer Protection of the Virginia Department of Health as a planning document, approved and adopted by the Board, to implement Virginia's COPN law. Any decision to issue a COPN must be consistent with the applicable provisions of the SMFP.

The SMFP provides specific guidance for approval of certain medical care facility projects and is the primary document used by the Department and the regional health planning agencies for determining public need for additional services. The SMFP includes (i) specific methodologies for projecting the need for medical care facility beds and services, and (ii) procedures, criteria and standards for the review of each type of COPN application.² The SMFP methodologies rely in large measure upon Virginia Health Information data collection showing utilization of services at existing providers.

Except for changes required by legislative mandate, the Department has not updated the SMFP since the first promulgation of the SMFP in 1993. Beginning in 2004, the Department began the process of revising the SMFP. The goal of the revisions was to update the criteria and standards to reflect current national and health care industry standards, to remove archaic language and ambiguities, and to create a more user friendly document by consolidating all portions of the SMFP into one comprehensive document. In 2005, the Department deferred action on draft final SMFP revisions to give the Commissioner a chance to review additional comments. In 2006, the Department held a series of meetings of an advisory committee of stakeholders (including the Virginia Hospital & Healthcare Association, The Medical Society of Virginia, the Virginia Health Care Association, the Virginia Association of Nursing Home Administrators, the Virginia Association of Regional Health Planning Agencies and the Board of Health) to resolve many of the issues with the revised SMFP. The last advisory committee meeting was held in October 2006, and the revised proposed SMFP was presented to the Board at the end of 2006.

Some of the revisions in the last draft of the revised SMFP include changes to occupancy levels for psychiatric beds, travel time standards for neonatal special care services, volume standards for CT services, and requirements for obstetrical services. The new services criteria for CT were revised from an average of 4,500 procedures per existing CT scanner to 10,000 procedures per existing and approved CT scanner. The volume criteria for proposals for increasing the number of CT scanners in an existing service were increased from an average of 3,000 procedures to 10,000 CT procedures

per scanner. The volume criteria for new MRI services were changed from an average of 4,000 procedures per MRI scanner to 5,000 MRI procedures per existing and approved MRI scanner. Furthermore, significant discussion also took place on such issues as the inclusion of preparation and clean-up time in the calculation of OR hours for hospitals and about facility specific need calculation methodologies.

The changes mentioned above were included in the last revised draft made available for public comment. The final revised draft of the SFMP has not been released to the public and is currently under administrative review. After administrative approval, there will be a 30-day public comment period, which will likely be during this summer. Final consideration and possible approval of the draft SMFP by the Board will likely occur in the fall.³

IV. Conclusion.

The 2007 Session began with a flurry of COPN bills, and although only HB 2546 survived to be signed into law, important changes were made to COPN program that could lead to a more efficient and streamlined COPN process. Together with important revisions expected in the revised SMFP, health care providers and their advisors should expect to see important changes in Virginia's COPN regulatory landscape in the near future.

NOTES

Patrick C. Devine Jr. is a partner in Williams Mullen in Norfolk and co-chair of its Health Care Section. Mr. Devine is a past chair of the Health Law Sections of both The Virginia Bar Association and the Virginia State Bar. He is included in *The Best Lawyers in America* (both for health and for corporate, mergers and acquisitions law) and in *Virginia Super Lawyers* and *Virginia Business* "Legal Elite" for health law. He is a graduate of Hampden-Sydney College and the University of Richmond School of Law and received his Master's in Law and Taxation from the College of William and Mary School of Law.

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This article is provided as an educational service and is not meant to be, and should not be construed as, legal advice.

1. Some of the less controversial bills included HB 1630 (adjusting the previously amended COPN authorization for three continuing care facilities that were established for the care of retired military personnel and their spouses or widows or widowers), HB 1691 (eliminating the requirement for a transition to the elimination of medical care facilities), and HB 1992 (authorizing the issuance of COPNs for the relocation of nursing home beds under certain circumstances). All of the COPN bills discussed in this article can be viewed at the Virginia General Assembly Legislative Information System (<http://leg1.state.va.us/>).

2. The SMFP is essential to the implementation of the COPN program, as it provides the criteria and standards for the full range of capital expenditure project categories that require review, including general acute care services, perinatal services, cardiac services, general surgical services, organ transplantation services, psychiatric and substance abuse services, mental retardation services, mental rehabilitation services, diagnostic imaging services, lithotripsy services, radiation therapy services, miscellaneous capital expenditures, and nursing home services.

3. To receive additional information on the SMFP revision process and to be placed on the COPN distribution listing, please contact Carrie Eddy, Senior Policy Analyst, Office of Licensure and Certification, Virginia Department of Health at carrie.eddy@vdh.virginia.gov.

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