THE GRAAPVINE

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Spring 2003

From the president's desk

by Warren Teeter

I have been honored this past year to serve as president of the Administrators in Academic Psychiatry. I wanted to thank the 120+ members and the Board for their efforts in making AAP such an outstanding professional organization. Our very talented membership and leadership are the essence of our strength. I am grateful for the guidance **Alex Jordan** (U Washington), immediate past-president, provided through midyear until his career transition to Surgery at U Washington. **Janet Moore** (Michigan State) came to our rescue by completing Alex's term as immediate past-president for the last half of the year.

Dan Hogge (U Utah), president-elect, and his Education Committee have done an outstanding job planning our Saturday, April 26, 2003 Spring Conference in Atlanta in conjunction with the Academic Practice Assembly annual conference April 27-29. Not only will we be reenergized professionally, Atlanta is a beautiful city in which to make and renew friendships.

The Board of Directors, in a conference call recently, decided several issues, some of which will require changes to the By-Laws and a vote of the membership at our annual meeting in April. Briefly, these include establishing a By-Laws Committee; requiring board approval for publishing products of AAP origin; waiving first-year new member dues; rolling over membership dues for new members replacing an existing member; increasing our membership dues from $75 to $100 effective 2004; immediate past-president and president do not have to be elected each year if they are in the progression process; and allowing our AAP reserve funds to be invested in secured, interest bearing accounts. Those proposals requiring membership approval will be communicated to you in advance of our conference.

We are proud of our achievements during this past year. These include growing and replenishing our membership (now up to 120+ members), keeping our conferences fresh and attractive to our attendees, strengthening the collaborative efforts between AAP and the Psychiatry Chair's group (AACDP), building on our 2002-2003 strategic plan, and continuing with our effective governance through quarterly board meetings.

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Administrators in Academic Psychiatry

Inside this issue

Comings and goings

If there are new AAP members in your state, please feel free to call them and personally welcome them to our organization. One of the things that makes AAP special is its friendly members! The hospitality offered by a personal contact will surely be appreciated.

AAP wishes to extend a warm welcome to the following new members:

Edward Kagan
U Medicine & Dentistry of NJ
(856) 482-9353

Patricia Levins
Medical College of Georgia
(706) 721-6718

AAP wishes good luck to the following members who have left their positions in Psychiatry:

William Dorr
Washington U (St. Louis)

President's message

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Again, I appreciate the leadership and support of the AAP board members:
Dan Hogge (University of Utah), President-Elect; **Pat Sanders-Romano** (Albert Einstein SOM), Secretary; **Brenda Paulsen** (University of Arizona), Treasurer; **Kevin Johnston** (Indiana University), Membership Director; **John Digangi** (University of Massachusetts), Member-at-Large, **Jim Landry** (Tulane University), and **Nishith Patel** (Mayo Clinic), Members-at-Large; and **Janet Moore** (Michigan State University), Immediate Past President.

Thanks also to **Jan Price**, (U Michigan) for her overall dedication to AAP and hard work as editor of the GrAAPvine.

I'll leave you with a small philosophical thought. If anyone ever asked me what I felt my mission statement is in life is, I'd probably say, "Somehow, some way, I hope when it's time to leave this world, as a result of my being here, I've made it a little bit better place than it was when I came." I hope through your work in behavioral health care administration, somehow, some way, you recognize that you've made this a better world for others as a result off your being here.

I look forward to seeing many of you at our Spring conference in Atlanta. Please contact Dan Hogge (Dan.Hogge@hsc.utah.edu) if you have any questions about the meeting. Please e-mail me at wteeter@wfubmc.edu or phone (336) 716-3544 if you have any questions or suggestions regarding AAP. I have been honored to serve as your president.

MacLeod to be honored during conference

Norman MacLeod, one of the founders and a charter member of Administrators in Academic Psychiatry, will be honored during the Spring Educational Conference in Atlanta, Georgia on April 26, 2003.

Although Norm has stepped down from a leadership role in AAP, his presence continues to be felt through his many contributions to the growth and development of our organization. He was part of the planning committee that met in Chicago in 1985 to draft bylaws and plan the implementation of AAP under the umbrella of the Academic Practice Assembly. He served as the first Secretary from 1986-1989, in the presidential progression from 1989-1992 and was the first editor of The GrAAPvine (then AAP Grapevine). Later, while serving on the APA ASIG Council he wrote a regular article for our newsletter to keep us informed of the business of our parent association.

While many people have contributed over the years to the formation and growth of AAP, Norm's vision, leadership, and enthusiasm laid a firm foundation for the successful organization we have become today. It is because of his many contributions to Administrators in Academic Psychiatry that the Board of Directors voted unanimously to honor Norman MacLeod.

2003 annual spring conference plans

We are excited and look forward to seeing you at our annual Administrators in Academic Psychiatry spring educational conference on Saturday, April 26th, in Atlanta, Georgia. The conference site is the Atlanta Marriott Marquis Hotel and our program is preview to the MGMA/ Academic Practice Assembly annual conference April 27-29, 2003. Hotel reservations can be made by calling 404-521-0000. Make sure you tell them you are with the Medical Group Management Association conference to get the group rate of $189/night.

The theme of this year's APA program is "Leadership for a New Era of Academic Medicine: Running on the Cutting Edge Using Technology, Innovation and Personal Touch." In addition to our preconference program on Saturday, AAP will be hosting an break-out session on Sunday from 2:00-3:15 pm.

We are pleased to have **Karen Milner, MD,** Medical Director of the Psychiatry Emergency Service, University of Michigan and Medical Director, Washtenaw County Community Supports and Treatment Services as our William J. Newel lecturer presenting "The Academic-Public Partnership." **Kevin Johnston** (Indiana University) will outline how his department developed and implemented a mission based faculty compensation plan. **Nish Patel** (Mayo Clinic) will discuss promoting research efforts in psychiatry. **Narriman Shahrokh** (University of California - Davis) will give us insights into personal enrichment. Another favorite, "Will You Take Two Minutes?" will provide attendees the opportunity to interact and exchange ideas with our peers. Additionally, we will have our annual business meeting and election of officers during Saturday's luncheon.

Our Sunday APA break-out will feature **Sara Larch, FACMPE**, Chief Operating Officer, University Physicians Inc., University of Maryland who will present "Denial Management - How to Track Denials if Your Computer Won't."

For those of you who plan on arriving early enough on Friday, April 25th you will need to mark on your registration form if you want us to make reservations for you for an informal dinner that night. After our Saturday meeting we'll enjoy our traditional AAP dinner at a local restaurant.

We know you will be richly rewarded for having attended so please plan on joining us. If you have not received our brochure or if you have any questions, please contact **Dan Hogge** at 801-581-8803 or Dan.Hogge@hsc.utah.edu or our Membership Director, **Kevin Johnston at** 317-274-2375 or kjohnsto@iupui.edu. We look forward to seeing you in Atlanta.

Not quite an adventure!

Scheduling our annual adventure in Atlanta has proven to be something of an adventure itself! Because the APA conference schedule changed this year, our usual Sunday day trip couldn't be organized. Since we'll have to be back for the AAP break-out session at 2:00 pm, a morning trip is all that we can do. But, planning something on a Sunday morning proved problematic since most venues don't open until noon.

I did find something that will allow us to step back into history - even if it's not quite adventuresome. In Grant Park, about 3 miles from the hotel, is the Cyclorama, an 1880's-style "virtual reality" tour of the Battle of Atlanta. The Atlanta Cyclorama houses one of a few remaining examples in the world of

an art form that was popular at the end of the 19th century, before moving pictures. A cyclorama is a huge, 360-degree three-dimensional cylindrical painting viewed from a rotating platform. This one is a 42-foot-high cylindrical oil painting, 358 feet in circumference (on about 16,000 sq. ft. of canvas) depicting in meticulous detail the events of the Battle of Atlanta, July 22, 1864. It took eleven artists twenty-two months to complete.

The fascinating story of Cyclorama's development and restoration is related in video format near the auditorium entrance. Cyclorama's central theme is Gen. John B. Hood's desperate attempt to halt Sherman's advance into the city. Comprehensively narrated, and complete with music and sound effects including galloping horses and cannon fire, it vividly depicts the troop movements and battles of the day in which the Confederates lost 8,000 men and the Union lost 3,722.

We can complete our outing with a stop at a local restaurant for lunch before returning to the conference for some "real reality." It may not be of the same caliber as some of our other adventures, but we can still share some camaraderie - which is, after all, why we have adventures!

The College corner
ACMPE by the numbers

by David Peterson, FACMPE

The updated membership statistics for the **American College of Medical Practice Executives (ACMPE)** just became available. There are 4,245 members divided into the following categories: 2592 Nominees, 1142 Certified Medical Practice Executives, 347 Fellows, 6 Life Certified Medical Practice Executives, 152 Life Fellows and 6 Honorary Fellows. Two AAP members are currently quite active in the certification process. **Jim Landry** (Tulane) is submitting the paperwork to complete the oral component of the certification exams, his final of the three components and **Rich Erwin** (University of Missouri) is scheduled to take the essay portion of the exam this month in Savannah, also his final component of the three. We wish them both the best of luck.

There's seems to be a Top 10 list for just about everything nowadays so with apologies to David Letterman, here's my version of 10 reasons to join the ACMPE.

#10: Camaraderie: There is always something to be said about being part of a group of people dedicated to improving themselves and their profession.

#9: Publications: Membership has it's privileges and biannually receiving *The College View* and access to other ACMPE-sponsored publications is one of them.

#8: Committee Work: There is plenty of opportunity to "be heard" within the ACMPE. Members have a strong voice in governance along with setting and maintaining membership and credentialing standards.

#7: Mentorship: Need a mentor? Want to mentor? The ACMPE offers both.

#6: Networking: Can one know too many people? There are a wide variety of venues offered to identify and interact with fellow members.

#5: Competitive Edge: Board Certification and interacting at a high professional level arms one with a competitive advantage at work and in the marketplace.

#4: Board Certification (and the Body Of Knowledge Corollary): The peer-reviewed, 3-part exams provide the opportunity to verify and test one's knowledge of medical practice management.

#3: CMPE: The Certified Medical Practice Executive credential indicates board certification.

#2: FACMPE: A Fellow in the American College of Medical Practice Executives credential is the "highest level of distinction that can be earned in the medical practice management profession."

#1: Personal Satisfaction: Numbers 2 through 10 offer a great deal of personal gratification and professional reward.

Since this is a column of numbers, I notice that by my count, this is my twentieth submission *to The GrAAPvine*. It's a good opportunity for me to thank the newsletter's editor, **Jan Price** (University of Michigan), and the **AAP leadership** for offering valuable newsletter space to the College for this column. Jan has been an indulgent editor and the AAP leadership has been supportive of the College. Both are greatly appreciated.

For more information on joining the ACMPE or the certification process, contact the ACMPE directly at (303) 397-7869 or contact David Peterson, FACMPE at (414) 257-7227, e-mail at peterson@mcw.edu or at the Department of Psychiatry and Behavioral Medicine, Medical College of Wisconsin, 8701 Watertown Plank Road, Milwaukee, Wisconsin 53226.

Need a conference brochure?
See our website at
http://www.adminspych.org

Behavioral health groups publish "Learning from Each Other: Success Stories and Ideas for Reducing Restraint/ Seclusion in Behavioral Health"

In an effort to capture the good ideas that are in use throughout the country to lessen the need for restraint and seclusion with psychiatric patients, several national associations have teamed up to publish *Learning from Each Other: Success Stories and Ideas for Reducing Restraint/Seclusion in Behavioral Health.* This 42-page publication was created by the American Psychiatric Association (APA), American Psychiatric Nurses Association (APNA), and the National Association of Psychiatric Health Systems (NAPHS) with support from the American Hospital Association (AHA) Section for Psychiatric and Substance Abuse Services (SPSAS).

The document was developed with extensive input from behavioral healthcare providers throughout the country – front-line staff members, clinical leaders, behavioral health administrators, and system executives who have been working with patients and families to reduce the use of restraint/seclusion and to improve care within their facilities. It was then reviewed and edited by multi-disciplinary experts.

The publication is intended to be a compendium of strategies that direct care providers and administrators may want to consider as they continuously evaluate and update their facilities' comprehensive policies and practices. The document may also help families and consumers understand the thought processes of clinicians as they work to develop an organizational culture that maximizes patient dignity and safety. The publication demonstrates the value of an ongoing dialogue with consumers and families as an integral part of healthcare providers' practice and as a critical part of the development of sound policy related to the use of restraint and seclusion.

To share the best thinking from the field, the sponsoring associations are making the complete text widely available at no charge on their web sites (http://www.naphs.org, http://www.psych.org, http://www.apna.org, and http://www.aha.org). The web sites also include suggestions to help organizations make use of the material in staff training and education.

"Media, accrediting, regulatory, and legislative bodies have focused national attention on the use of restraint and seclusion in behavioral health organizations," said APA Charles Riordan, M.D., Chair, APA Committee on Standards and Survey Procedures. "These groups have consistently challenged the professional community to provide leadership in determining ways to minimize circumstances that give rise to restraint or seclusion use and to maximize safety when restraint and seclusion are used. The purpose of this project is to identify a body of high-quality clinical and operational information related to restraint and seclusion that can be recommended to the field."

"The document confirms what we know: patient-centered care is the heart and soul of an effective organization," said APNA Executive Director Jane White RN, CS, DNSc. "This document is full of ideas for creative approaches that both clinical and administrative staff members can take today to maintain a culture of safety that will lead to improved patient satisfaction and improved quality of care."

"By providing our members with the tools to think through the entire process of maintaining a culture of safety, we hope to educate system leaders and facility staff members about the value of early, coordinated intervention with this most important – and vulnerable – population as well as the need for adequate resources to deliver what we know works," said NAPHS Executive Director Mark Covall.

"Patients are the priority for America's hospitals," said Bari Johnson, Director of the AHA Section for Psychiatric and Substance Abuse Services. "This document is one more tool to help physicians, nurses, and the entire hospital team deliver high-quality care. We're all committed to working together with consumers, families, clinicians, regulatory and accrediting agencies, Congress, and others to continuously improve patient care and to maintain a culture of safety."

Learning from Each Other: Success Stories and Ideas for Reducing Restraint/Seclusion in Behavioral Health provides information on current knowledge and thinking about care for youth and adults with psychiatric, emotional, and behavioral problems. The document is based on literature reviews, extensive structured interviews with members of the sponsoring organizations, and ideas solicited from the behavioral health field. The document gives ideas on leadership, staff education, assessment, treatment planning, documentation, milieu management, and debriefing. It also includes a list of helpful resources and publications. In addition, an appendix of sample forms, assessment tools, and checklists is posted along with the document on the associations' web sites.

(Press release of the American Psychiatric Association (APA), American Psychiatric Nurses Association (APNA), National Association of Psychiatric Health Systems (NAPHS) and American Hospital Association (AHA) Section for Psychiatric and Substance Abuse Services (SPSAS).

Suggested reading

Good to GREAT: Why Some Companies Make the Leap and Others Don't by Jim Collins, HarperCollins Publishers, New York, NY, 2001, 320 pages.

As lifetime students of organizational management, we have become accustomed to reading about management principles, styles of leadership and companies that have been very successful over time and what has constituted that success. However, it's pretty unlikely that we studied/examined companies that were *good* at what they did to make the leap to become *great*.

The majority of companies that have been great traditionally started out great and never had to make that leap. In the very first chapter of this book, the author points out that the biggest impediment to a good company becoming great is that the company is good. Most people are satisfied with things being good, and they don't see the need to make the leap to great. As we all know, being good can be very comfortable. (A big bonus is that the concepts the author identifies in this book can be applied to our personal lives as well.)

Jim Collins and his team undertook a five-year research project to uncover the variables that make the transition from good to great happen. The initial selection process included 1,435 Fortune 500 companies from the 1965-1995 listing. This list was pared down three more times until there were 11 companies identified as going from good to great. To be in the final cut, these companies had to sustain the good to great transition for at least 15 years. The companies included: Abbott, Circuit City, Fannie Mae, Gillette, Kimberly-Clark, Kroger, Nucor, Philip Morris, Pitney Bowes, Walgreens and Wells Fargo. The performance of these companies was extraordinary and averaged cumulative stock returns of six times the general market.

A control group of comparison companies that either failed to make the leap or if they did, failed to sustain the leap, was also selected. The author then did an in-depth analysis of the variables that contributed to their success. Findings were surprising and included:

- Popular CEO's recruited from outside of the organization most likely had a negative impact on the company becoming great.
- Structure of a CEO's compensation packages were not a key indicator of success.
- Great companies did not spend more time on long-range strategic planning than good companies.
- Great companies did not limit their focus on what to do to become great, they also focused on what they should **not** do and on what they should **stop** doing.
- Technology could not cause the transformation but could accelerate it.
- Mergers and acquisitions played no role.

"Good to GREAT" companies did not need to motivate people, create alignment or manage change. These things happened naturally by placing the right people into the right jobs. Initially, most of these companies were not aware of the magnitude of the transformation to come. None of the great companies were in great industries at the time. They became great because of the conscious choices that were made. Other findings included:

- Most of the leaders were quiet, reserved, self-effacing and came from within.
- *People* were not the most important asset, but the "*right people*" were. The CEO had to "get the *right* people on the bus, the *wrong* people off the bus and the *right* people in the *right* seats. Then they figured out where to go."
- You could never lose faith that you would prevail in the end. In the meantime, reality confrontation throughout was essential.
- Just because a particular service/product was your main business didn't mean that you could be the best at it. If you couldn't be the best in it, you shouldn't let it form the basis of your company. An important distinction here is that it's not about having a goal that you will be the best or a plan to become the best, it's an *understanding* of *what* you can be the best at. This is referred to as the Hedgehog Concept.
- Your company must have a "*culture* of discipline" which includes disciplined people, disciplined thought, and disciplined action. This culture eliminates the need for hierarchy, bureaucracy and excessive controls. A "culture of discipline" combined with an "ethic of entrepreneurship" begets star performance.
- Technology was not used to begin the transformation process; carefully selected technologies were implemented to facilitate the process.
- The transformation never happened suddenly because of a single incident or change.

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> Rather, it was likened to "relentlessly pushing a gigantic flywheel in one direction, turn upon turn, building momentum until a point of breakthrough and beyond."

This book is very well written and easy to read. There are many interesting case stories, thorough explanations of essential concepts and a section on frequently asked questions. The author addresses such things as how to deal with nepotism, how great CEO's lose their star performance and why "stop doing" lists are more important than "to do" lists.

The implications of this book have far reaching effects, not just for your professional life but for your personal life as well. When you are working in an environment that you are truly dedicated to and you are doing what you really are best at, both your professional and personal life moves toward "greatness". There is a symbiotic effect. You do not have to change jobs to have a great life. The author challenges you to get involved in something that you are truly passionate about and something that you are naturally great at. He indirectly motivates you to get excited about your life and live to your fullest potential.

As Jim Collins so capably explains in the last paragraph of this book: "When all these pieces come together, not only does your work move toward greatness, but so does your life. For, in the end, it is impossible to have a great life unless it is a meaningful life. And it is very difficult to have a meaningful life without meaningful work. Perhaps, then, you might gain that rare tranquility that comes from knowing that you've had a hand in creating something of intrinsic excellence that makes a contribution. Indeed, you might even gain that deepest of all satisfactions knowing that your short time here on this earth has been well spent, and that it mattered."

(Reviewed by Radmila Bogdanich, administrator of the Southern Illinois University department of psychiatry).

Ask the experts

Editor's note: Our colleagues are our best resource for information, and the active use of the listserv demonstrates how valuable we think our collective expertise is. I'd like this to be a regular column, so please consider taking a few minutes to summarize the thoughts you've been able to glean from our experts on your most pressing issues.

At the University of Michigan, on weekends and holidays, all Adult faculty in the department rotate coverage of the Adult inpatient unit, including visiting the inpatient unit each day. Because these weekend rounders are not familiar with the patients, the care and decision-making is minimal. To add to the problem, our residents are assigned to the Psychiatry Emergency Service on weekends, and only come to the inpatient unit to work up admissions. They do not generally round with the weekend faculty, meaning that there is often a lack of information given to the attending. Additionally, these rounders are often not well versed in writing notes that comply with E&M standards (rather than psychotherapy notes), which creates lower coding and charges on the weekends.

Several respondents to the listserv question said that they cover weekends in the same way as we do at Michigan, and have the same problems. Others had some interesting approaches to the issue.

To address the problem of medical decision making and discharges, a few of the departments use what **Brien Cushman** (U Calgary) called the "transfer of care." Variations of this transfer include making a courtesy call between the weekday and weekend attending; having the clinical team provide a list of patients they believe to be ready to be discharged; and having the discharge planning as complete as possible prior to the weekend (i.e., disposition arranged, prescriptions prepared and pending orders written). **Terry Gevedon, MD** (U Kentucky) explained that providing these "helps" has increased the number of weekend discharges from almost zero to frequently now.

Although all of our faculty are required to provide coverage at least one weekend a year, we experience problems getting them to volunteer. Several departments have overcome this reluctance by paying faculty for this extra coverage. I couldn't extrapolate unit size from the numbers so could not determine if the pay is consistent across departments. However, there was a range of payment from $1100/day to $100/hour, $60/patient and various amounts in between.

Finally, one department has a policy to discharge on Fridays since few services are available on the weekend anyway. For those patients who aren't ready for discharge, weekend day passes may be issued to assess the patient's ability to return to home and the community. For all other patients, a psychiatrist on call (all faculty take a turn) covers the reduced volume.

CMS clarification of teaching physician documentation

On November 22, 2002 the Centers for Medicare and Medicaid Services (CMS, formerly known as HCFA) published a revision to the Medicare Carriers Manual Part 3- Claims Process. Physicians at teaching hospitals had felt that the documentation requirements for billing CMS beneficiaries was at best burdensome and had asked for simplification and clarification of acceptable and non-acceptable language to indicate their participation in patient care when working with residents or personally performed services. CMS has provided several scenarios to illustrate acceptable documentation for services provided personally by the teaching physician, for services provided by the resident with the teaching physician physically present, and for services provided in the absence of the teaching physician.

There are 5 major points in these revisions.

1. The revised language makes it clear that for evaluation and management (E/M) services the teaching physician does not have to repeat documentation already provided by the resident. CMS goes on to state that codes assigned to services billed by teaching physicians will be a combination of the documentation of both resident and the teaching physician's documentation.
2. Unless the service is provided under the Primary Care Exception, the teaching physician must still be present for the key portions of the service and still must document that physical presence in a personally authored note in the medical record. If the teaching physician conducts his/her portion of the service separately from the resident, the teaching physician note should reflect that he/she performed the key portions but may refer to the resident's note. If there was no resident participation, the attending note should document as in a non-teaching setting.
3. Resident documentation of the physical presence and participation of the teaching physician by the resident is no longer sufficient.
4. CMS has delineated what they consider to be unacceptable language used by teaching physicians in their documentation of resident supervision. Unacceptable documentation includes: "Agree with above", "Rounded, Reviewed, Agree", "Discussed with resident. Agree", "Seen and agree", "Patient seen and evaluated", countersignature or doctor number alone. These are not acceptable because it is not possible to determine whether the teaching physician was present, evaluated the patient, or had any involvement with the plan of care.
5. The revisions also clarify policies for services involving medical students. Students may participate in the performance of a billable service in the presence of the attending or the resident and may document services in the medical record. However, the documentation of an E/M service by a student that may be referred to by the teaching physician is limited to documentation related to the review of systems and/or past family/social history. The teaching physician may not refer to a student's documentation of physical exam findings or medical decision making in his or her personal note. If the medical student documents E/M services, the teaching physician must verify and redocument the history of present illness as well as perform and redocument the physical exam and medical decision making activities of the service.

The full text of the transmittal can be found on the web at www.cms.hhs.gov/manuals/transmittals and click on File R1780B3 (11/22/02).

Medicare intermediaries required to notify providers of denial reason

Effective April 1, 2003, carriers will be required to give providers notification of a denial when it is based on a local medical review policy (LMRP). A new remittance advice (RA) remark code, N115, has been established for use in these notifications. All newly established LMRP edits must contain the new RA remark code (if applicable) in addition to the current applicable messages. By October 1, 2003, every LMRP edit must contain the new RA remark code (if applicable) in addition to the current applicable messages. Providers must know why their claims are denied, so they can decide whether to appeal those claim denials and so they will know how to avoid such denials, if desired, in the future.

The program memorandum outlining this change is available at http://www.cms.gov/manuals/pm_trans/AB02184.pdf.

Impact of the HIPAA privacy rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements and research contracts

NOTICE: NOT-OD-03-025
National Institutes of Health (NIH)

The purpose of this GUIDE notice is to provide an overview of how the HIPAA Privacy Rule may affect NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements and research contracts.

The Department of Health and Human Services (DHHS) issued final modifications to the STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION, the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information. The Rule was enacted to increase the privacy protection of health information identifying individuals who are living or deceased, and to regulate known and unanticipated risks to privacy that may accompany the use and disclosure of personal health information. The Privacy Rule is not an NIH regulation. It is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule, including some grantees and contractors, must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply). The OCR website (http://www.hhs.gov/ocr) provides information on the Privacy Rule, including a complete Regulation Text for the Privacy Rule.

I. The Privacy Rule and Research: Roles and Responsibilities Grant Applicants and Contract Offerors

The Privacy Rule applies to researchers classified under the Rule as covered entities (i.e., a health care clearinghouse, health plan, or a health care provider that electronically transmits health information in connection with a transaction for which DHHS has adopted standards under HIPAA). The Rule may also affect researchers who obtain individually identifiable health information from covered entities through collaborative or contractual arrangements. Decisions about whether and how to implement the Privacy Rule reside with the researcher and his/her institution. A set of decision tools on "Am I a covered entity?" are available from the OCR website (http://www.hhs.gov/ocr/). Researchers should review this and other information on the Privacy Rule and then discuss with their appropriate institutional officials (e.g., Office of Research, legal counsel, etc.) to learn how the Rule applies to them, their organization, and their specific research project. OCR and the Department of Justice (DOJ) may impose civil or criminal penalties, respectively, on covered entities that fail to comply with the Rule.

When conducting investigator-initiated research that involves a covered entity the Privacy Rule may influence the environment in which the research takes place. As a result, implementing the Privacy Rule may affect the feasibility, design, and cost of the research.

The roles of several Federal agencies regarding the Privacy Rule are described below:

Office for Civil Rights (OCR) – Oversight and civil enforcement responsibility for the Privacy Rule are under the auspices of OCR, DHHS.

Department of Justice (DOJ) – Enforcement of the criminal penalties for violations of the Privacy Rule is under the auspice of DOJ.

National Institutes of Health (NIH) – Development of educational materials for researchers, in collaboration with other DHHS research agencies, is the role of NIH. NIH is not involved in enforcing or monitoring compliance with the Privacy Rule.

II. How the Privacy Rule may Impact the NIH Grant & Cooperative Agreement Application and Research Contract Processes

A. New and Competing Continuation Grant & Cooperative Agreement Applications/Contract Proposals – *Review and Funding Grant and Cooperative Agreement Applications:* When conducting investigator-initiated research that involves a covered entity the Privacy Rule may influence the environment in which the research takes place. As a result, implementing the Privacy Rule may affect the feasibility, design, and cost of the research. As with any issue that can affect feasibility, design, and cost, researchers should continue to follow the instructions in the PHS 398 (http://grants.nih.gov/grants/funding/phs398/phs398.html) and discuss such issues, as needed, in the research plan and budget sections of the application.

It is important to note that the Privacy Rule does not replace or act in lieu of existing regulations for the protection of human subjects found in 45 CFR 46. Therefore, instructions in the Human Subjects section of the PHS 398 remain the same. Researchers should continue to consider issues of privacy and confidentiality as they affect the

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adequacy of protections of human subjects from research risks, and when appropriate, address these issues in the Human Subjects section of the research plan.

New and competing continuation grant & cooperative agreement applications will continue to be evaluated using the existing review criteria found in PHS 398 and reviewers will continue to use the existing NIH Instructions to Reviewers for Evaluating Research Involving Human Subjects http://grants.nih.gov/grants/peer/hs_review_inst.pdf.

Some Requests For Applications (RFAs) and Program Announcements (PAs) may request applications for specific areas of research and could indicate the need to provide a plan for acquiring or accessing data under the Privacy Rule. In such cases, the review criteria listed in the RFA or PA could be augmented to include adequacy of such plans and reviewers would evaluate these.

NIH funding decisions for new and competing continuation grants and cooperative agreements will continue to be based on scientific merit, programmatic need, and availability of funds. Program staff will continue to discuss and seek resolution of issues or problems noted in the summary statement – including issues noted regarding the effect of the Privacy Rule – with investigators prior to funding.

Research Contract Proposals: When performing research under a research contract that involves a covered entity, the Privacy Rule may affect the environment in which the research takes place. As a result, implementing the Privacy Rule may affect the feasibility, design, and cost of the research. As with any issue that can affect feasibility, design, and cost, researchers should discuss the issues, as needed, in the technical and business proposal sections of the contract proposal.

It is important to note that the Privacy Rule does not replace or act in lieu of existing regulations for the protection of human subjects found in 45 CFR 46. Therefore, instructions in Section L of the solicitation remain the same. Researchers should continue to consider issues of privacy and confidentiality as they affect the adequacy of protections of human subjects from research risks, and when appropriate, address these issues in the Human Subjects section of the technical proposal.

For new contract solicitations, reviewers will use the evaluation criteria set forth in Section M of the solicitation and continue to use the existing instructions found in Manual Chapter 6315-1 (http://www1.od.nih.gov/oma/manualchapters/contracts/6315-1/). Some Requests for Proposals (RFPs) could indicate the need to provide a plan for acquiring or accessing data under the Privacy Rule. In such cases, the review criteria listed in the RFP could be augmented to include adequacy of these plans and reviewers would evaluate these.

Researchers should continue to consider issues of privacy and confidentiality as they affect the adequacy of protections of human subjects from research risks, and when appropriate, address these issues in the Human Subjects section of the technical proposal.

NIH funding decisions for new research contracts will continue to be based on technical merit and cost. The technical evaluation report will include a discussion of issues and problems, including any noted regarding the Privacy Rule. The contracting officer will include these issues and problems during discussions held with offerors in the competitive range and seek resolution prior to award.

B. Non-Competing Applications/Contracts – Progress Monitoring *Grants and Cooperative Agreements:* During the period of award, principal investigators of grants and cooperative agreements communicate progress and issues about the research with NIH program and grants management staff in annual progress reports, as well as on as-needed bases. If situations are encountered that significantly delay the study, change the study design or procedures, or change the costs of the research, these issues should be communicated to NIH staff as soon as possible. This same practice applies to significant research delays or problems associated with acquiring or accessing data under the Privacy Rule; issues should be communicated to NIH staff. NIH staff will evaluate situations on a case-by-case basis.

Research Contracts: During the contract period of performance, the contractor communicates progress and issues about the research to the contracting officer and project officer on a regular and as needed basis. If it encounters situations that significantly delay the study, change the study design or procedures, or change the costs of the research these should be communicated to NIH staff as soon as possible. In this same manner, significant research delays or problems associated with acquiring or accessing data under the Privacy Rule should be communicated to the contracting officer and project officer who will evaluate the situation on a case-by-case basis.

III. Where to obtain information on the Privacy Rule

As part of its oversight role, OCR is providing a number of publications on implementing the Privacy Rule through its web site at http://www.hhs.gov/ocr and http://www.hhs.gov/ocr/hipaa/. As the research community, DHHS, OCR, and NIH gain experience with

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implementation of the Rule, additional FAQ's and publications will be posted on these OCR web sites.

NIH staff can provide assistance in locating educational materials on the Privacy Rule. For general questions about how the Privacy Rule may affect the review, funding, and progress monitoring of NIH grants, cooperative agreements and research contracts, please contact program and grants management staff in the NIH Institutes relevant to your area of scientific interest.

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HIPAA privacy regs will have impact on use of patient health info in research

by Edward Goldman, Assistant General Counsel, University of Michigan Health System

Under the HIPAA privacy regulations, once a patient has acknowledged receipt of a Notice of Privacy, health care providers may use the information collected about and from that patient for normal operations (such as treatment, payment and business operations, or TPO). Under the regulations, research is not a part of treatment, payment or business operations, so there are separate rules for research usage of protected health information (PHI).

Right now, the federal government has research regulations in a series of rules called the "Common Rule" (rules common to 17 federal agencies). These rules require all research to be approved by an Institutional Review Board (IRB). The IRB reviews the research, decides if subject consent is required and reviews the consent process and documentation. If consent is not required, the IRB grants a waiver of consent. Waivers are generally granted in situations where it would not be practical to obtain permission from patients. (For example, if the care was provided 20 years ago and the patient cannot be located today).

The Common Rule will remain in effect, but after the HIPAA privacy regulations become enforceable (April 14 of this year) they will add new criteria intended to enhance patient privacy protection:

- HIPAA will add requirements to the existing waiver process. These will include requiring researchers to present assurances that the use or disclosure of the PHI will involve only "minimal risk" to privacy; that they have a plan to protect identifiers; that there is a plan to destroy identifiers at the earliest opportunity; that there will be no reuse or re-disclosure of the PHI; and that the research would not be possible without a waiver.
- HIPAA will add specific language to the authorizations that willing research participants sign to give their permission for their PHI to be used. These additions include statements such as a description of the PHI, purposes of use, and the possibility of re-disclosure. Under the added HIPAA requirements, the authorizations also must provide an expiration of the authorization and tell the participant how to revoke their authorization.
- Research databases with PHI also come under HIPAA guidelines for privacy so that patients must specifically allow their information to be included. Databases for clinical care are considered part of a hospital's normal operations (TPO) and do not have the same restrictions as those for research under HIPAA. However, use of these data for research must still be approved in advance by the IRB.

According to HIPAA privacy regulations, information is not PHI if it is "de-identified." This requires removing 18 identifiers, such as names, addresses, social security numbers, registration numbers, photos, device identifiers, URLs, biometrics, etc.

If patient information is turned into a "limited data set" (containing geographic information, but no street addresses, for example) there is no need for patient permission. Two other major exceptions to getting patient authorization are research using PHI of patients who are no longer living and reviews "preparatory to research," in which PHI is reviewed solely for the purpose of deciding whether or how to conduct a research project.

An important condition of HIPAA's privacy regulations requires that an accounting be kept of all uses of PHI, even research conducted under a waiver. This means a patient has the right to ask whether their information has been used or looked at for research. If asked, the institution must provide this information to the patient.

(Article reprinted with permission from The Star*, the employee newsletter of the University of Michigan Health System, January 15, 2003 and was intended to provide general information on the subject).*

Mothers and sons

Three women in Miami are bragging about their devoted sons.

Mrs. Miller says, "Mine is so devoted he bought me a trip around the world first class."

Mrs. Jones counters, "Mine is more devoted. On my birthday he flew in 300 people from Brooklyn ... and catered!"

Mrs. Berg chimes in, "You want to hear devoted? Three times a week my son goes to a psychiatrist. One hundred and twenty dollars an hour he pays him. And who does he talk about the whole time? ..... Me."

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