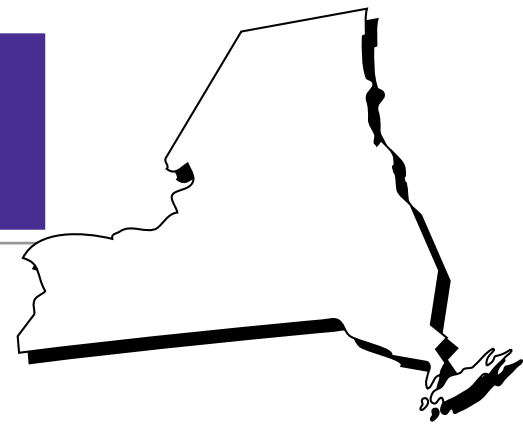


THE BULLETIN

NEW YORK STATE PSYCHIATRIC ASSOCIATION

Fall 2009, Vol. 52, #3 • Bringing New York State Psychiatrists Together



President's Message: Should the APA Have an Assembly?

By C. Deborah Cross, MD

When I became President of the New York State Psychiatric Association three years ago, I assumed the most basic duty of representing the interests of New York State psychiatrists to the leadership of the APA and the rest of the membership. I also assumed the role of representing New York psychiatrists in the APA Assembly. I have written many times in this column about various aspects of the APA Assembly and, hoping I won't bore all of you who have patiently read through these columns, I want to write about it once more. The reason I am choosing to write about it now is that the very existence of the APA Assembly is in jeopardy.

I have tried to explain the function of the Assembly in these columns, but the role of the Assembly is a complex and diverse one—which is very difficult to explain in a short column. Others (namely Dr. Jack McIntyre and Dr. Herb



C. Deborah Cross, MD

Peyser) have written about the history of the Assembly and its crucial role in the development of the APA. When the APA was formed in 1844 there was no Assembly—and there were no District Branches. At that time the APA was called the Association of Medical Superintendents of

the Insane! The District Branches (originally "Societies") began in 1925. Later, in 1949, the DBs pushed to create an Assembly of District Branches, which was to be an advisory body to the "Council" (now the Board of Trustees). This relationship between the Assembly and the Board (of an advisory nature) continues to this day, even though there have been attempts through the years to change the Assembly to something more resembling the American Medical Association in which the Board is governed by the House of Delegates.

The APA Board of Trustees is a relatively [See **President's Message** on page 2]

HIPAA Update

By Rachel A. Fernbach, Esq.

Signed into law in February, 2009, the American Recovery and Reinvestment Act ("ARRA") is a comprehensive economic stimulus bill that includes provisions aimed at encouraging widespread use of health information technology. The ARRA incorporates the Health Information Technology for Economic and Clinical Health Act ("HITECH"), which provides \$19 billion in federal funding in support of health information technology initiatives.

HITECH makes extensive changes and clarifications to the HIPAA privacy and security regulations. In addition, Title IV of the ARRA creates a new financial incentive program for Medicare and Medicaid providers who adopt health information technology in their practices.

Under HITECH, all health care providers that are subject to HIPAA are required to amend their HIPAA documents no later than February 17, 2010. The HIPAA documents that must be amended include the HIPAA Business Associate Agreement, the HIPAA Notice of Privacy Practices and the HIPAA Policies and Procedures. In addition, as of September 23, 2009, in the event of a breach of health information, HIPAA covered entities are required to provide notice of such breach to any affected individuals and to HHS.

In order to assist members understand and comply with the new HIPAA rules, NYSPA has prepared a guidance document outlining the changes and specific steps that individual providers must take. To download the guidance document, please click on the "HIPAA UPDATE" link on the homepage of the NYSPA website (www.nyspsych.org). In addition to the already available guidance document, NYSPA will be revising all of its HIPAA templates, which will be available shortly for download and printing on the NYSPA website. Finally, NYSPA will be providing members with a template for a

Notice of Breach in the event a breach occurs.

The following is an overview of the HIPAA changes, which go into effect February 17, 2010:

Breach Notification: HIPAA providers must provide notice to all affected individuals in the event of an unauthorized or inadvertent breach of unsecured personal health information. The new notice requirement applies to all breaches occurring on or after September 23, 2009.

Business Associates: HIPAA privacy and security rules will now apply directly to business associates who will be subject to the same civil and criminal penalties that apply to covered entities. Also, business associates must provide notice of any breach of information.

Restrictions on Disclosures: Covered entities must always comply with a patient's request for restrictions if the information is to be sent to a health plan for payment or health care operations purposes and the disclosure relates to products or services that were paid for solely out-of-pocket.

Minimum Necessary Rule: Congress directed HHS to issue guidance clarifying the meaning of the term "minimum necessary."

Accounting of Disclosures: Individuals will now be entitled to receive an accounting of routine disclosures (e.g., for treatment, payment and health care operations purposes) of their health information if the health information is maintained in an electronic health record system.

Prohibition on Sale of Electronic Health Records or PHI: Covered entities and business associates may not receive direct or indirect remuneration in exchange for PHI, unless a valid HIPAA authorization has been signed by the patient, which includes such permission. Exceptions to the rule include sale of PHI in connection with

[See **HIPAA Update** on page 2]

Albany Report: NYSPA Co-Sponsors Veterans' Mental Health Training Initiative

By Richard J. Gallo

NYSPA recently partnered with the National Association of Social Workers - New York State Chapter and the Medical Society of the State of New York to sponsor the newly instituted Veterans' Mental Health Training Initiative (VMHTI), a program aimed at training mental health providers in mental health issues affecting returning veterans and their families. VMHTI was made possible through a grant from the NYS Office of Mental Health and is supported by an advisory panel of policy experts, clinical experts, veterans and family members.

As service members return home, they and their families are often in need of expert mental health care, yet there is a short supply of mental health professionals who are adequately trained in veteran-specific mental health issues. In addition, recent studies demonstrate unprecedented rates of alcohol and substance abuse among deployed and

returning service members who are struggling to cope with the war and its effect on themselves and their families. In order to provide training in veteran-specific mental health issues, the VMHTI is planning five regional training sessions throughout New York State for social workers and other mental health providers that will focus on the unique needs of returning veterans and their families. The sessions include information for providers on assessing and treating combat-related mental health disorders, such as post-traumatic stress disorder, traumatic brain injury and substance abuse disorders, as well as family issues related to deployment and re-entry. The trainings are offered free of charge and are open to mental health professionals, members of the military, veterans and their families.

The first training session, entitled "Symposium on Enhancing Community

[See **Albany Report** on page 3]



From left: Frank Dowling, MD, Vice Chair of the Emergency Preparedness Committee for the Medical Society of the State of New York, Ray Cardona, Executive Director, National Association of Social Workers - NYS Chapter, NYS Senator Charles J. Fuschillo, Jr., Rachel Fernbach, NYSPA Associate Executive Director, and NYS Assemblyman David McDonough

Healthy Minds Premieres Nationwide on Public Television

The *Healthy Minds* series is premiering nationally this month. In the NYC Metropolitan Area, the series is being broadcast on Channel 13 Saturdays at 7am with repeats on WLIW 21 Sundays at 9:30am and Tuesdays at 11:30pm. All of the ThinkBright digital public television stations in New York State are broadcasting the series on Tuesdays at 2:00pm and 8:30pm.

Hosted by Jeffrey Borenstein, M.D., each half-hour in the 16-episode series humanizes a specific mental health condition through inspiring personal stories and interviews with leading researchers and experts, who provide the latest information about diagnosis and treatment. *Healthy Minds* covers a wide range of topics, including autism, depression, chemical dependency, post-traumatic stress disorder, eating disorders, and bipolar disorder, to bring viewers a better understanding of disorders that can affect anyone at any age.

All 16 episodes are available for viewing on line at www.wliw.org/healthyminds.

Healthy Minds is made possible in part by New York Academy of Medicine <<http://www.nyam.org/>>, NARSAD <<http://www.narsad.org/>>, the van Ameringen Foundation <<http://www.vanamfound.org/>>, the New York State Office of Mental Health <<http://www.omh.state.ny.us/>>, Value Options <<http://www.valueoptions.com/>>, and the New York City Department of Health and Mental Hygiene <<http://www.nyc.gov/html/doh/html/home/home.shtml>>. National distribution of *Healthy Minds* is made possible by a grant from the American Psychiatric Foundation <<http://www.psych-foundation.org/>>, which is the charitable and public educational arm of the American Psychiatric Association <<http://psych.org/>>.

THE BULLETIN

NEW YORK STATE PSYCHIATRIC ASSOCIATION

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Information for Contributors

The Bulletin welcomes articles and letters that NYSPA members will find timely, relevant, and compelling. Articles should be between 750 and 1500 words (three to five double-spaced manuscript pages) and letters no more than 750 words. All submissions must be made electronically, preferably by email to the editor. All authors are encouraged to also provide a photograph of themselves which will be printed alongside their article.

Information for Advertisers

The Bulletin welcomes advertisements from both NYSPA members and commercial enterprises. Total circulation averages 5,500 copies per issue. *The Bulletin* is received by members of the American Psychiatric Association who belong to a district branch in New York State. *The Bulletin* is also sent to the leadership of other district branches across the United States and to New York State legislators, medical libraries, and science writers. *The Bulletin* is published quarterly. Both classified advertisements and display advertisements are available. Please contact the editor for current rates and media requirements. NYSPA members receive a discount of 50% off the basic classified ad rate.

The opinions expressed in the articles or letters are the sole responsibility of the individual authors, and may not necessarily represent the views of NYSPA, its members, or its officers.

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FROM THE EDITOR'S DESK... By Jeffrey Borenstein, MD

This edition of the Bulletin has information about important issues which impact psychiatry in NYS. The President's Message provides an overview of the APA Assembly and how potential changes may affect how NY is represented in the national



Jeffrey Borenstein, MD

organization. We have a review of the effect of the federal law on NYS. We also have an update about changes in HIPAA. We report on an important initiative to train mental health professionals on issues affecting returning veterans and their fami-

lies. We have an article about Comparative Effectiveness Research and potential effects this may have on the practice of psychiatry. Finally, I am proud to report on the national distribution of the *Healthy Minds* public television series for which I have the privilege and honor of serving as host. ■

President's Message continued from page 1

small body (and growing even smaller through downsizing!), while the Assembly has increased from being just representative of District Branches to including representation of Residents, "Early Career" Psychiatrists, Minority and Underrepresented Psychiatrists (Hispanic, African American, etc.), and Allied Organizations (Child, Geriatric, etc.). The Assembly is a large, diverse and often extremely unwieldy body. Discussions on the floor of the Assembly can be raucous, and tedious, sometimes accomplishing little. However, it is democracy at work! Everyone is heard—and every viewpoint is accorded a hearing. Through this process ultimately much significant work is accomplished. The psychiatrists who make up the Assembly give up a lot of their free time, and a lot of their professional time—usually uncompensated if they are in private practice! They spend hours reading tons of material, they go to numerous meetings, spend enormous amounts of time on conference calls and on emails. All because they believe that the ordinary psychiatrist needs someone to represent their interests in the national arena of psychiatry. They also feel that the Board of Trustees MUST be held accountable to the membership! The Assembly gets reports from the Board and the APA officers. Tough questions are asked and accountability is demanded. In the last 10 years the Assembly has been the one part of the APA that called the Board to task for allowing a past Medical Director to spend down virtually all of the APA's monetary reserves.

The APA officers are elected by the APA membership at large. However, the average psychiatrist knows little to nothing of those running for the prestigious offices of President, President Elect, Secretary, etc. There are Area Trustees and sometimes these psychiatrists are known at the local level, and we in New York are often fortunate in that our Area Trustees are able to reach out to our membership. This is not generally the case in other Areas where you have one Trustee for 15 States.

Because the candidates for national office are often not known, there is little interest in voting—the average vote return for 10-15 years has been around 30-35% of the membership! When a member does vote, they often vote on "name recognition" so that we now have a President who many say they voted for because they recognized his name from a textbook!

As I referred to above, there have been attempts over the years to have the Assembly be the controlling body of the APA (similar to the AMA) as opposed to the small Board of Trustees. This has not occurred. At present, in fact, because the APA is experiencing a significant negative financial situation, there is a push to downsize the Assembly to such an extent that it will be virtually non-existent. What is occurring now is that the Board has given the Assembly the task of cutting its budget by 20%, with the potential of another 20% cut next year. Because the way in which to achieve this cut has been left to the Assembly, we, the Assembly, are now in the midst of fighting among ourselves as to how to do this. It is an extremely unpleasant state of affairs, in which every Area and State is trying their best to represent their constituents. I, as your President, am committed to making sure that New York is treated as fairly and equitably as any other state. This is a difficult task since New York has been seen by many in the Assembly as being overly represented in the past. We are one of only 3 states with more than 1 District Branch. Most DBs are States, while New York has 13 DBs. Other members of the Assembly often forget that New York has over 4,000 psychiatrists! Some proposals for downsizing the Assembly would have New York cut to where we had less representatives than many other states—a situation that I and your other officers find intolerable. There is a push to equalize the representation by state. Some states, such as Wyoming have only 27 members, and there is no way that we in New York would consider any kind of "equalization" of representation by states in

which New York would have similar representation as Wyoming! Another proposal by well meaning members of the Assembly has been to decrease the meetings of the Assembly from 2 meetings a year to 1 (at the Annual Meeting). Your New York officers and I feel that this would be the death blow to the Assembly, since the argument would be that if we only needed to meet once a year, why did we even need to meet! It seems to me that there are a number of people currently on the Board who feel that the APA does not need an Assembly!

As long as the APA has a "bicameral" form of government, that is a Board and the Assembly (even though the Assembly is only a consultative body), there is the recognition that the average psychiatrist has a forum to get his or her views heard. With only a small Board of Trustees, that WILL NOT OCCUR! Can you imagine trying to get your views heard if you only had access to President Obama and his Cabinet? The US has both executive and legislative branches and everyone can reach their Senator or Representative. You have your DB representative and the officers of the New York State Psychiatric Association to hear your concerns and make sure they are addressed at the national level.

This November, the Assembly will have to decide how to cut 20% from the current budget. We (NYSPA) have submitted what we feel to be a fair and equitable plan to achieve the necessary budget reductions and still enable us to reasonably represent you, the New York psychiatrist. We are committed to making sure that you continue to have a voice in the APA. NYSPA officers and your DB representatives need your support now as we approach the November Assembly meeting. Please let us hear from you as to how we can make sure your views are heard in Washington. As always, please contact me at deborahcross@usa.net. ■

HIPAA Update continued from page 1

public health activities; research; treatment; sale or merger of the covered entity; work done by a business associate; and provision to an individual of a copy of his or her PHI. This change will not take effect until six months following promulgation of final rules implementing this section.

Access to Information in Electronic Format: If a covered entity maintains an electronic health record for an individual, the individual may request access to the information in an electronic format.

Marketing and Health Care Operations: The new rule clarifies the

interaction between marketing activities and health care operations activities.

Opt-Out of Fundraising: Language providing individuals with the chance to "opt-out" of fundraising communications must be presented in a clear and conspicuous manner. Any opt-outs elected will be treated as a revocation of any prior authorization.

Enhanced Enforcement: HIPAA civil money penalties are increased and criminal penalties are added for individuals or employees of covered entities who violate HIPAA.

Finally, starting in 2011, health providers who accept Medicare and/or

Medicaid and who are meaningful users of electronic health record technology may be eligible to receive incentive payments. Medicare providers only who are not meaningful users of electronic health record technology by the end of 2014 will be subject to a reduction in their Medicare fee schedule starting in 2015. To assist members, NYSPA has prepared a summary of the new Medicare and Medicaid incentive programs that is available on the NYSPA website. In addition, NYSPA will provide members with further information regarding the incentive programs as it is made available. ■

New York State Insurance Department Confirms Parity in New York

By Rachel A. Fernbach, Esq.

The New York State Insurance Department recently confirmed that the federal parity law will require certain employers in the state to provide full parity with respect to visit limits, inpatient days of coverage, copayments, coinsurance amounts, deductibles and in and out-of-network coverage. This mandate will significantly expand mental health and substance use disorder benefits for many New Yorkers.

The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 requires health plans that cover mental health or substance use disorder benefits to provide full parity with other medical and surgical benefits, with respect to treatment limitations, financial requirements and out-of-network benefits. The federal parity law applies to all new plan years starting on or after October 3, 2009.

Insurance Department Circular Letter No. 20, issued on September 10, 2009, details the direct impact that the federal law will have on Timothy's Law, New

York's mental health mandate, and another state law that requires coverage for outpatient substance use disorder treatment. NYSPA is very pleased to report that the Insurance Department has adopted many of NYSPA's positions and suggestions regarding implementation of the federal parity law.

An interesting threshold issue is the method for determining whether an employer is large or small. The federal parity law counts total employees, while Timothy's Law counts only employees who are eligible for health insurance. For example, an employer may have 60 total employees but only 35 of them may be eligible for health insurance. As a result, this employer would be considered a small group under Timothy's Law but a large group under the federal law. Even though the employer is considered to be a small group for the purposes of Timothy's Law, its employees will still be entitled to parity in mental health and substance use disorder benefits under the federal law.

The following is a summary of the key points of Circular Letter No. 20:

Treatment Limitations: Large employers must provide parity in outpatient visit limits and inpatient days for mental health and substance use disorder benefits.

Financial Requirements (Inpatient): Large employers may not impose greater copayments or coinsurance amounts for inpatient mental health and substance use disorder benefits or subject those benefits to a separate deductible.

Financial Requirements (Outpatient): The Insurance Department will continue to permit insurers to apply either the primary care or specialty care office visit copayment to mental health or substance use disorders benefits. However, insurers applying the specialty care copayment must be able to demonstrate that the specialty care copayment is also applied to substantially all of the medical or surgical benefits offered in the policy or contract. Provided, however, that HMOs may not apply the spe-

cialty care office visit copayment to outpatient substance use disorders benefits, in accordance with separate state guidelines.

Outpatient Substance Use Disorder Benefits: New York's minimum requirement for outpatient coverage of substance use disorder benefits will be fully expanded into a requirement for parity in outpatient *and inpatient* coverage of substance use disorders.

Cost Exemption: The federal parity law includes a one-year cost exemption for health plans that are able to demonstrate that compliance will result in a 2% increase in total costs in the first plan year and a 1% increase in subsequent years. The Circular clarifies that even if an insurer is granted such exemption, the insurer must still provide all mental health and substance use disorder benefits required under New York State law.

To view the text of Circular Letter No. 20, please use this link: http://www.ins.state.ny.us/circltr/2009/c12009_20.htm ■

Albany Report continued from page 1

Capacity to Meet the Needs of Returning Service Members and their Families," was held on Thursday, September 17, 2009, at Hofstra University on Long Island. At the event, VMHTI awarded the Public Service Award to New York State Senator Charles J. Fuschillo, Jr., in recognition of his leadership and support of the Veterans' Mental Health Training Initiative in the New York State Legislature.

After accepting the award, Senator Fuschillo stated "those of us who have never served in combat missions may never understand the dangers our troops live with on the battlefield, but

programs like this will allow professional social workers to become specifically aware of the challenges veterans face when they return to their families and civilian life."

NASW-NYS Executive Director Reinaldo Cardona explained that "the impetus behind this project was a response to both NASW membership and citizen requests to increase the quality of, and access to care for veterans and their families, what it morphed into was a commitment to providing New York's veteran population with the best care possible. Senator Fuschillo stood shoulder to shoulder with us in this endeavor...his support and sponsorship

of this project, even in a considerably difficult budget year, never wavered. He and his staff believed in the project from its inception and worked tirelessly with the Chapter's policy staff to make it a reality."

NYSPA was represented at the event by Rachel A. Fernbach, Associate Executive Director, who added "creating a highly trained mental health provider workforce is a crucial first step in the identification of mental health and other neurological issues that disproportionately affect returning veterans and their families. Awareness and identification of the issues will enhance the ability of veterans to be referred for psychiatric

and neurological assessment, which will in turn lead to greater access to necessary medical care and treatment for individuals in need."

Subsequent Training Institute dates and locations are as follows:

- October 23, 2009
Lake Placid – High Peaks Resort
- November 20, 2009
Brockport – SUNY Brockport
- April 23, 2010
NYC – Fordham University
- May 21, 2010
Hudson Valley – SUNY New Paltz ■

Comparative Effectiveness Research: An Introduction

By Barry B. Perlman, MD

On February 17, 2009, within a month of his inauguration, President Barack Obama signed into law the American Recovery and Reinvestment Act (ARRA) of 2009, the \$787 billion economic package meant to stabilize and stimulate the nation's economy. Contained within the Act was \$1.1 billion dollars designated for Comparative Effectiveness Research (CER). CER looks to improve healthcare by development of evidence based practice guidelines. These guidelines are based on systematic reviews and synthesis of existing basic and clinical research, through data mining of registries and cohort studies to understand the natural progression of diseases and factors which influence their clinical outcomes, among other approaches.

This large infusion of funds into an already evolving area of research placed CER at center stage of the push towards the national healthcare reform and thus evoked a great deal of controversy. Important stakeholders immediately started weighing in on the issue, either

supporting it as a path to more rational and cost-effective therapeutics or condemning it as antithetic to individualized, person centered care. Each group's arguments often seem marked by hyperbole. How the CER is structured, what questions are asked, and how its findings are engrafted into clinical decision making will be of the utmost importance to physicians, including psychiatrists, other providers, as well as to patients/ consumers and their families. My interest was piqued.

Clearly, no one should fear well done research. Rather, it should be embraced as invaluable in informing clinical care. However, concern should arise when research findings are used to dictate clinical decisions rather than to inform them. This is so because medical science is complicated, difficult to control and dynamic. This observation is especially true for clinical science due to the multiplicity factors impacting on each individual's healthcare outcomes, such as genetic makeup, environment, comorbidities, etc. In addition, the com-

plexity of research methodologies make it notoriously easy to misinterpret data and misapply them to practice and policy. Individuals will need to be better informed in order to advocate for their own care while stakeholders use information to advocate with government and other powerful organizations, such as health insurers, that increasingly decide which therapies will be accessible and covered. In an age marked by calls for adherence to "best practices" and "evidence based medicine" it is important to be aware of the shallow and narrow nature of many of those clinical guidelines. Skepticism and humility about clinical research is warranted. We would do well to remember an interchange about Miles, the protagonist in Woody Allen's 1973 movie *Sleeper*. A doctor observing Miles' behavior notes his request for "wheat germ, organic honey and Tiger's milk." Another informs that, "Those are the charmed substances that some years ago were thought to contain life-preserving properties." The first continues,

"You mean there was no deep fat? No steak or cream pies ...?" The response was, "Those were thought to be unhealthy ... precisely the opposite of what we now know to be true."

That humorous yet cynical interchange draws attention to the often tenuous basis of what we think we know. While there are undoubtedly domains in which CER is likely to yield clear guidance, perhaps with medical devices, comparative therapeutics, etc., its ability to provide clear pathways is not always evident. Many recent clinical examples support the need for skepticism but not cynicism. Recent examples of radical reversals of policy within relatively short time frames have emerged from clinical research in the fields of cardiology, hypertension, endocrinology, and psychiatry, among others. They have involved positions of federal agencies, the JCAHO, and medical specialty societies. For example, as evidence mounted that antidepressants, when pre-

[See **Research** on last page]

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scribed for children and adolescents, might evoke suicidal thoughts, the FDA in 2004 required that a "black box" warning be added to medication package inserts. It now seems that the FDA's warning resulted in a decline in the prescribing of antidepressants for the identified groups and, inadvertently, resulted in the reversal of what had been a declining rate of youth suicide. The take away message from these episodes is of the overriding power of government, accreditation organizations, and large health insurers' policies to influence care on a vast scale, for better or worse.

Why choose to raise the matter of CER for the readers of the Bulletin? First, ARRA directed the Institute of Medicine (IOM) to identify national priorities as research questions to be addressed by CER using ARRA funds. The Institute Of Medicine, which had no psychiatrist or other mental health expert on its Committee on CER Priorities, published its recommendations on 6/30/09 which addressed a wide array of mental health concerns. (The American Psychiatric Association was invited to present very brief comments at one of the Committee's listening sessions.) It is unclear whether the questions brought forward in the report were ones those in the field would have posed and whether if translated into research they will provide direction to the field's critical concerns. (The IOM Report is easily reviewed on the web.) I suggest that NYSPA members familiarize themselves with the report and the CER process as envisioned.

Second, as the IOM research topics and others are undertaken as CER is pursued, we must wonder how and by whom they will be applied to public policy and individual plans of care. Let me provide an example from the arena of psychopharmacology. What psychopharmacologic treatments will be considered acceptable and paid for in caring for persons with serious and persistent mental illness such as chronic schizophrenia remains an important and exemplary question. It is a fact that to date there has been no research which shows a "significant" benefit from using two atypical antipsychotics simultaneously. Anecdotally such cases exist and there is some support for using two atypicals in the clinical literature. These medications are very expensive and costly to state Medicaid programs or private insurers. Given this background, the question then is, what latitude will clinicians retain when treating persons who have remained refractory to the evidenced based care laid out in clinical guidelines? NYS OMH will be using its PSYCKES data base to identify cases for which two "atypicals" are being prescribed as part of its quality indicator study. The NYS Office of the Medicaid Inspector General, charged with rooting out fraud and abuse, planned to review such cases as part of its 2008 work scope but deferred that project pending the PSYCKES results. The question is should all such use be adjudged improper? Scientifically the resounding answer should be "no." As a matter of policy,

the answer is less certain. From a statistical perspective, the absence of a finding of significance does not mean there may not be meaningful subgroups or individuals which would benefit. The criteria of large clinical trials are so broad as to obscure what might be important treatment effects for subgroups. As statisticians know, the absence of evidence is not evidence of absence (of an effect). Once government focuses on a practice, such as the "inappropriateness" of prescribing two atypical antipsychotics at once, doctors become far less likely to treat a patient with the "targeted" combination, even when they have exhausted standard options, due to their fear of being cited. Likewise, if time consuming hoops are created as barriers to such prescribing by insurers, will time pressed doctors make the necessary effort to clear the hurdles? Will clinics, whose quality may be judged on such criteria, discourage their physician employees from going beyond the "approved" prescribing practices when they perceive a need? Can we be comfortable that an insurer's policy is clinically not financially based given that industry's problematic record? Will large governmental agencies or insurers be nimble enough to adapt their policies to clinical science's rapidly changing landscape? (Perhaps, going forward, the use of data mining on vast data sets such as those of Medicaid, Medicare or private insurers may help identify those for whom less recognized approaches to care such as the two "atypicals" is beneficial, if

there are enough cases to provide the statistical power to perform the analysis.)

Alerted to CER and what we may expect over the coming years as this process gains momentum, how might readers think about this movement? Readers should welcome the use of CER and other avenues to improved treatment and recovery. However, we should do so with open yet skeptical minds. Dr. Jerry Avron, Professor of Medicine at Harvard and Director of the Harvard Interfaculty Initiative on Medications and Society, in a recent article in the New England Journal of Medicine, asks, "What is the moral responsibility of the physician to care for a patient for whom the best therapy may not meet the conventional standards of cost-effectiveness?" He continues, "These aspects of the debate will need to continue as we begin to implement CER with this vital new funding." While all cannot become statisticians or methodologists, we can inform ourselves and raise questions and concerns with policy makers, both governmental and private sector, when they promote or act to circumscribe access to a variety of approaches to care. ■

Dr. Perlman is the Director of the Department of Psychiatry at Saint Joseph's Medical Center in Yonkers, N.Y. He is a NYSPA Past President and is currently Chair of the NYSPA Committee on Legislation. Dr. Perlman is also a past Chair of the NYS Mental Health Services Council.

Can your claims examiner pass this test?

1. What does Axis III of the DSM-IV classification signify?
2. What is tardive dyskinesia?
3. What is the significance of the "Tarasoff" decision?
4. How often should lithium be monitored?
5. Which population is most at risk for suicide?
6. What precautions should be taken before administering ECT?
7. What is the definition of suicidal ideation?

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