**President’s Message: Transparency of Clinical Research** By Barry Perlman, M.D.

O
casionally there are critical issues that crystallize an issue and set the scene in a contest of events which propsel change. Such was the case when Eliot Spitzer, the NYS Attorney General, said at the Rainbow Room on June 7, 2004, that the New York State Medicaid program was going to implement the use of forge-proof prescription drug trial databases at their inception as a preclusion to their publication in the journals. Leading Democratic Senators were said to be considering legislation which would require the creation of a national database in which trial results would be registered and the results of which would be publicly available. Hopefully, a major pharmaceutical company, Merck, announced support for the creation of a federally supported prescription drug trial database.

Within days of the announcement of Spitzer’s action, newspaper articles appeared announcing an astounding series of “after shocks.” The A.M.A. adopted a resolution, with the strong support of the psychiatric delegates to the House of Delegates, calling for the creation of a database of all clinical drug trials undertaken in this country. The editors of several prestigious medical journals, members of the International Committee of Medical Journal Editors, announced that they were considering a requirement that pharmaceutical companies register clinical drug trials at their inception as a preclusion to their publication in the journals. Leading Democratic Senators were said to be considering legislation which would require the creation of a national database in which trial results would be registered and the results of which would be publicly available. Hopefully, a major pharmaceutical company, Merck, announced support for the creation of a federally supported prescription drug trial database.

NYSPPA, along with all medically important organizations, is extremely concerned that physicians and physicians must be able to rely on the clinical data available to us when we read the professional literature. As psychiatrists, we firmly endorsed the need for effective responses is as important to us as it is to those we treat. The bedrock foundation of our relationship with our patients is trust. As psychiatrists and physicians we must be able to be able to rely on the clinical data available to us when we read the professional literature.

**Medicare Reverses to Reveal Reimbursement Disallowance Made in Violation of HIPAA Rules** By Rachel A. Fernbach, Esq., NYSPA Staff Attorney

B
cause of the vigilance and persistence of one New York psychiatrist, Medicare auditors across the country will now comply with federal HIPAA privacy protections for psychotherapy notes. Ann-Marie Paley, M.D., a NYPPA member practicing in Queens County, had been randomly selected to participate in the Medicare Comprehensive Error Rate Testing program (CERT). The CERT program is a nationwide effort by the Medicare program to detect billing errors by reviewing patient records to determine whether the records support the claim paid by Medicare. Medicare has contracted with various private medical review companies to conduct these random reviews of all medical services provided under the Medicare program throughout the country.

Dr. Paley was asked to provide patient records for one patient over two different dates of service. In response, she provided certain portions of the medical records to the CERT contractor. The psychiatrist was able to provide portions of the records containing separately maintained psychotherapy note material. Dr. Paley correctly asserted that, under HIPAA, psychotherapy notes may not be disclosed only pursuant to a written patient authorization. Medicare, however, did not provide any such patient authorization.

When Dr. Paley refused to submit the psychotherapy note portion of the records to Medicare for review in connection with the CERT audit, the claims were disallowed and the Medicare carrier recouped the payments. After Dr. Paley contacted Mike Stein, the NYSPPA officer, Mr. Stein sent a letter to the GHI Medical Department explaining that the demand for repayment in Dr. Paley’s case was improper and in violation of the federal HIPAA Standards for Privacy of Individually Identifiable Health Information (the “Privacy Rule”).

Mr. Stein explained that the Privacy Rule applies to all health plans, health care providers and health care payers who transmit personal health information electronically. Medicare Part B is a health plan that is subject to HIPAA and the Privacy Rule because it is specifically listed in the Privacy Rule’s definition of the term ‘health plan.’

In general, under the Privacy Rule, person

Medicare/Medicaid Crossover

Late in the evening on Wednesday, August 11, the New York State Legislature hammered out the final details of the $301 billion State budget for Fiscal Year 2004-05. This budget is unlike other recent budgets in state history. The completed fiscal plan added a $2.1 billion to Governor Pataki’s proposed budget to escalate it to meet the state budget needs. In the face of that demand,ScrollView to Read More
President's Message

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published in peer reviewed journals or hear new data presented at psychiatric meetings. Without that confidence we cannot assure those for whom we prescribe the soundness of our judgments. For these reasons it has been disappointing to learn that important clinical evidence may not have been withheld when the outcomes of pharmaceutical company research weigh against the drug sales. Likewise, when pharmacological computer misrepresent claims about the safety of medications in promotion materials. Unfortunately when patients and their families learn that they have been deceived and possibly even exposed to the possibility of drug interventions purchased at considerable expense whose benefits may be marginal or non-existent it breeds cynicism and distrust of not only the drug company but also the prescribing physician. It is clear that physicians, dependent as we are on a relation of trust with our patients, cannot tolerate deception to rend the whole cloth of the healthcare system.

As an editorial in the New England Journal of Medicine began, “For many years, the registration in a public database of data from all clinical trials – from start to completion and reporting of results – has seemed a quixotic quest of some academicians, researchers, medical-journal editors, and librarians.” (2004; 345: 315-317) The possibility of a constructive resolution to a long recognized and simmering problem seems a quixotic quest of some academicians, researchers, medical-journal editors, and librarians.” (2004; 345: 315-317) The possibility of a constructive resolution to a long recognized and simmering problem.

Albany Report

from page 1

some of the members of the Timothy’s Law Campaign that the introduction as a means to jump-start the negotiations, the bill itself, was not supported by TIC.

As the end of the 2004 session loomed, there seemed to be a forthcoming compromise. During the remaining days of the session, the Albany Report continued its consistent communication with key members of the Senate and the Assembly in an effort to bridge the gap between the two bills. In an attempt to address one of the Senate’s concerns regarding the new bill, the Assembly clarified its position introducing a new bill (A.11694), which maintained broad coverage for both mental illness and chemical dependency, but also included a tax credit for small businesses to help defray any additional costs, only in the case of psychologists. Unfortunately, during the final hours of the last night of the 2004 regular session, it was announced that all discussions (not exclusive to parity) between the Senate and the Assembly had collapsed. The end result was the passage of two “one house” parity bills.

Scope of Practice

Although the 2002 social work licensure bill has yet to go into effect, several attempts to broaden the scope of language were proposed under the guise of “clean up” bills. These actions prompted both NYSPA and to its members.

APA Job Bank on NYSPA Website

The APA Job Bank is an interactive employment site which can be accessed directly from the home page of the NYSPA website. Psychiatrists looking for available positions or the opportunity to search the site by discipline, specialty, geographic location or to post their CV’s to the site. Employers interested in posting employment opportunities can do so through the NYSPA Central Office. NYSPA will receive royalties for all job posting contracts, provided that they are arranged through our site, so please encourage your colleagues to contact NYSPA if they are interested in posting a position.

To post a job opening on the APA Job Bank, or for additional information, contact the NYSPA Central Office by phone (516-542-0077) or by email (centraloffice@nyspsych.org).
Magellan Sends Out New Provider Contracts
By Rachel A. Fernbach, Esq., NYSPA Staff Attorney

NYSPA members enrolled in the Magellan network recently received a large packet from Magellan described as the “New Group Provider Participation Agreements.” The packet included four contracts for the Magellan indemnity and HMO plans together with five additional, two amendments, an EAP, attachment and six reimbursement schedules.

NYSPA Central Office has received numerous telephone inquiries asking about this offerer of agreements, addenda, amendments and new providers signing about various provisions in the agreements. In response, Seth Stein, NYSPA Executive Director, directed the committee to identify potential problem areas and issues in the contracts. A copy of the memo has been posted on the Members-Only Section of the NYSPA website (www.nyspsych.org). A letter was also sent to Magellan identifying these areas of concern in the Magellan contracts.

The following key issues and problems were identified:

- **Indemnification Requirements** - All provider contracts include a provision that requires the provider to “defend, hold harmless and indemnify” Magellan against any and all claims, liability, damages or judgments asserted against, imposed upon or incurred by Magellan in connection with or arising out of breaches that arise out of the acts or omissions of Provider or Provider’s employees, agents or representatives in the disposition of its responsibilities under this Agreement. NYSPA asserted that this clause conflicts with transfer of liability provisions in New York Public Health Law §4903(4) for HMO contracts and New York Insurance Law §4903(n) for indemnity plans. In his letter to Mr. Stein, Dr. Ferran argued that the cost of defense in a lawsuit brought against Magellan alleging a claim that may ultimately be determined to be the sole responsibility of the psychiatric is the type of claim that should be borne by the individual psychiatrist. In addition to this legal issue, psychiatrists are unable to obtain coverage from Magellan’s contract indemnification because the APA-endorsed professional liability insurance program does not cover contractual indemnification.

- **Insurance Requirements** - The contracts require providers to maintain three types of insurance coverage: (i) professional liability, (ii) errors and omissions; and (iii) comprehensive general and/or umbrella liability. The APA-endorsed professional liability insurance program does not include coverage for errors and omissions as a distinct category from professional liability. If psychiatrists are unable to secure this type of coverage, they will not be able to comply with this contractual obligation and should be held liable for such damages. NYSPA members were permitted to strike the clause from the contract before signing.

- **HIPAA Privacy Rule** - Another major concern regarding the Magellan agreements is that there is no referral or incorporation of any requirement concerning the federal HIPAA Standards for Privacy of Individually Identifiable Health Information (the “Privacy Rule”). The Privacy Rule went into effect on April 14, 2003, and applies to all health plans, health care clearinghouses and managed care companies such as Magellan. As a covered entity under HIPAA, Magellan must comply with all provisions of the Privacy Rule, including specifying the minimum necessary requirement, the prohibition on conditioning authorizations and the special exceptions to the separately maintained psychotherapy notes. Mr. Stein provided Magellan with guidance on these topics and encouraged Magellan to revise the agreements to incorporate HIPPA requirements and principles where appropriate.

In conclusion, NYSPA represents its members in the hope that your comments and for psychiatrists to make an informed decision.

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In conclusion, NYSPA represents its members in the hope that your comments and for psychiatrists to make an informed decision.
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On October 22, 2003, identical ver-
sions of the Medicaid Psychiatric Hospi-
tal Fairness Act of 2003 were intro-
duced in the House (H.R. 3163) by Repre-
sentative Lloyd Doggett (D-TX) and in the Senate (S. 1771) by Senators Olympia Snowe (R-ME) and Kent Conrad (D-ND). The American Psychiatric Association, NAMI, the National Association of State Behavioral Healthcare Directors, the American Hospital Association, and the National Association of Psychiatric Health Systems support this measure.

Marcia Goin, M.D., who at the time was the APA President, wrote an October 2003 letter to Chairwoman Snowe supporting this proposed legislation.

Mr. Covall replied, "The logjam in general hospital psychiatric services in private hospitals, these hospi-
tals will be forced to close or downsize: "If more hospitals are forced to close or downsize then the problem will get much worse." The Medicaid Psychiatric Hospital Fairness Act of 2003 Mr. Covall explained why the Medicaid Psychiatric Hospital Fairness Act of 2003 would allow non-public psychiatric hospitals to receive appropriate reimbursement from the Medicaid program. And that is what it was intended to do. It was not a policy deci-
sion based on any medical considerations. It was a political decision and a financial decision. In fact, the Administration had promised that it would get the Medicaid program enacted into law.

As part of the White Paper that the IMD exclusion played in deinstitutionalization, Mr. Stein replied, "Clearly, the IMD exclusion, which eliminated Medicaid reimburse-
ment for adult patients (ages 21 to 64), was a factor in closures because the state was saving the money, but it was not a direct cause." Mr. Covall continued, "It made deinstitutionaliza-
tion more possible to government because it was reducing its costs. This was particularly true in the early days of deinstitutionalization and the dollars that were saved were not reinvested in community serv-
ces."

Mr. Stein continued, "It made the state look at state psychiatric beds differently … than they would have looked at them if 50 per-
cent of these beds had been paid by Medicaid."
It is currently proposed that the majority of the surplus will again be placed in the reserves as we still have less than a quarter of the 20 million dollars recommended for the Associations reserves. It is expected that the budget will continue to be at least $380,000 for district branch needs, as was allocated this year. The board also approved a merit pool for staff to exceed $475,000 to be funded from the American Fund. This is the seventh significant merit increase in several years. The Board will be discussing in October the further distribution of over $1,300,000. It has been a recommendation that a small percentage of the investments be in hedge funds, a much riskier activity than traditional invest- ment. While such investments are currently shown to have a good return, placing any percentage of the investments be in hedge funds—which leaves a question as to our policy of non investment in certain instruments. Let me say in passage.

A complete budgetary plan for 2005 will be approved in October. There is a cau-
sionary note however, as the net revenue projections for the annual meeting in New York at last year are lower than for this year in New York. Still not time to celebrate yet!!

MEMBERSHIP

The good news is a small but steady increase in the number of active members in the APA!! Thanks to each of you for your continued support and encourage colleagues to join! The previous controversy with Washington State, the ADA and the TBA on linking membership from the national APA has been successfully resolved with Washington State, and the latest move with Texas. The Board is awaiting a response from Texas as to what the practical issues are with their newly proposed method of “manager,” other than the ability to be a member without paying national dues. Area II has remained opposed to such strategies.

I am honored to have been elected to serve as Speaker of the Assembly of the APA and am particularly proud to hail from Area II where I had valuable experience as your NYSPA President from 1998 to 2002. NYSAPA is in capable hands under the leadership of Dr. Barse-Peltier and is served by an excellent body of officers and council members. This paper has chronicled a continuing array of significant contributions by NYSAPA benefiting the practitioners and patients in our state. Our lobby, headed by the Legislative Institute, is Director of more than 20 years, Seth Stein, remains abreast of legislative issues, and both have made important contributions also on a national level, working in tandem with APA in Washington on several important initiatives.

The Speaker serves as a voting member on the Board of Trustees, as a member of their Executive Board, on the Budget and Finance Committee, and attends meetings at the other six areas across the country during the year. New York is also well rep- resented in the Assembly by its Recorder, MYCH’s Stuart Barger, MD, and by its parliamentary, Ed Hanin, of the New York County DB and by its parliamentary, Ed Hanin, of the New York County DB and itself a Past Speaker. I am additionally provided with excellent counsel by our Area Trustee, Ann Sullivan and our prior Area Trustee, Herb Portrait. I would like to take this opportunity to provide a brief review of the Assembly’s history and then mention some of my goals for the Assembly for the coming year.

The Assembly, with representatives from all the district branches of our association, is meant to debate and represent the con- cerns of the members and, to generate action papers for approval and action by the Board of Trustees on the full range of issues facing psychiatry today. Any APA member can propose an action paper for his or her representative to bring forward for consideration by the Assembly. Consultation from relevant components on action papers is encouraged, and the Assembly members are broadly represented on APA councils and committees to facilitate the process. The Assembly meets twice before the Board meets each month and in November. The seven area councils additionally meet at least once before each Assembly meeting.

In 1952, from an interest of district branch members to have their representatives be able to influence the direction of the association, the bylaws of the association were amended to create Assembly District Branches. In 1953, the Assembly represented 16 district branches and 8,000 members. Representation for the next 25 years was entirely geographic. Then in 1978, minority/underrepresented groups were added to the council, and in 1984, 20 additional members in training were added. In 1994, a district branch with Assembly representa- tion from the state’s smallest specialty was organized, and in 1996 early-career psychiatrists joined. Over the next several years, other specialty organizations or individuals who representing subspecialties, were encouraged to provide non-voting liaisons, and now 17 “labeled organizations” are represented in the Assembly, and each has a vote. There have been many discussions about the optimal size and representation of the Assembly, and currently each district branch has at least one voting representative, and the district branch representatives have one voting representative for every 450 voting members or portion thereof (e.g., a districts branch of 1,100 would have three voting representatives). Currently, three states (California, New York, and Missouri) have more than one district branch. Geographical area councils were formed shortly after the Assembly was constituted (originally five, now seven) and the areas gradually began to meet between Assembly meetings.

This past year the Assembly devoted a ple- nary session to the topic of access to treat- ment, and as part of this session my Speaker-Elect forum addressed “treatment of Mental Illness in Jail and Prisons” with a panel including our President, Dr. Marcia Goi, who subsequently convened a summit in Washington, D.C., that involved key advisory groups and experts and addressed delivery of care to this popu- lation. A working resource document has been developed to assist states in working with and educate policy makers at local, state, and national levels. Reporting for the past five years, our state’s approximately 8000 people with mental illness in jails and prisons are in the New York City Metropolitan area, Rikers Island, de facto, the state’s largest psychiatric facility.

Health care is enduring financial and orga- nizational help to districts branches need- ing assistance in funding their infrastruc- ture, recruiting and maintaining members, and fighting legislative battles such as attaining nondiscriminatory insurance cov- erage for mental illness and substance abuse disorders, and the certification of prescription privileges for psychologists.

Though the role of the Assembly is to advocate on the size and approved action and initiatives can have a profound effect on influencing APA policy as they can have a profound effect on increasing definition of and attention to our organizational priorities, including increasing public awareness and unifying our resources for regional activities, and improving collaboration and communication regarding our activities, and improving collaboration and communication regarding our activities, and improving collaboration and communication regarding our activities, and.

I look forward to working with you in the coming year as your Speaker, and I urge all of you to contact me or your district branch Assembly representatives. Call them for information or to initiate an
I n Oneida County, this used to be a common scenario. People with seri- ous mental illness would get out of the hospital or jail, and they would have to wait for their Medicaid to kick in, which is on average 4 to 6 weeks. They would go that length of time without their medication, and, more often than not—because their mental health deterio- rated—they would end up recommitting a crime or end up back in the psychiatric unit of the hospital,” said Deborah Gibbs, a Principal Clerk for Oneida County and the Principal Clerk for the Oneida County Department of Mental Health.

This is less likely to occur now. Why?

One key reason is that Oneida County participates in NYS OMH’s Medication Grant Program. Via this program, New York State provides grants to participating counties, which, in turn, purchase psychi- atric medications and other services need- ed to prescribe and administer medica- tion. (This includes psychiatric visits relat- ed to prescribing or administering med- ication.)

Counties who elect to participate provide medication grant cards to eligible individ- uals. These cards can be used to obtain medications and these services while they wait for their Medicaid determination. Currently, 3,800 pharmacies in NYS par- ticipate in the program. There is no co- pay. After their Medicaid eligibility is determined, they are disenrolled from the program.

Current active for Medicaid because their Medicaid is deactivated while they are incarcerated.

Ms. Katz explained, “When we initially rolled the program out, our first priority was to get the jails and prisons to partici- pate because that is where we perceived the greatest problem to be. That’s the place where people were most likely to be...eligible for Medicaid but are not cur- rently active for Medicaid because their Medicaid is deactivated while they are incarcerated.”

Reflecting on the feedback she has received from county officials and others, Ms. Katz said, “I think it [the Medication Grant Program] has been very successful. We have gotten testimonials from a num- ber of counties that think this is one of the best things the state ever did. It does address a very real need.”

Ms. Gibbs agreed. “I can’t imagine not having this program—how they would react, what would happen to them. I think it is a wonderful human interest program,” she said.

She added, “I’m sure that the fact the individual does not decompensate as a result of receiving their medicine has a direct relationship to them not returning to the ER or jail.”

Ms. Gibbs noted, “The whole reason the program ever came to our county was because of the awareness of our mental health commissioner, Phil Endress, CSW, ACWS, MBA, in addressing this issue and the needs of these people to get their medications. He believes it’s an opportu- nity to enhance the lives of individuals.”

Basic Information

The enrollment process is slightly differ- ent for individuals leaving prisons, jails, or hospitals. Basically, designated employees from the jail, prison, or hospital assist these individuals in completing and submitting their Medicaid application and their one-page Medication Grant Program application.

Who is eligible for the Medication Grant Program according to Ms. Katz, individ- uals must meet the following criteria:

- They must be about to be discharged from a hospital inpatient unit or released from jail or prison.
- A designated employee, who helped the individual fill out a MGP enroll- ment form, must sign it, thereby, veri- fying that they believe the person is Medicaid eligible.
- The individual’s Medicaid application and MGP form must be submitted to the county Department of Mental Hygiene prior to or within seven days of leaving the jail, prison, or hospital.

Once the county has received the MGP application, it is forwarded to First Health, the Pharmacy Benefit Manager that OMH contracted with to help the counties administer the program. First Health enrolls the individual and notifies the county. The county provides the individual with a medication grant card.

In Oneida County, the whole enrollment process takes just several minutes. Ms. Katz explained, “I complete my portion of the paperwork which takes a few min- utes and fax the application to First Health, and then they fax it back to me within a couple of minutes. Finally, I type up the card, which is only four lines.”

She continued, “All recipients either have their card before they are discharged or pick up the card. With inmates, usually the transitional case manager from the jail will come here and pick up the card. That way the inmates have their card upon their release, which most often occurs at mid- night.”

Outcomes: Oneida County

When asked about measuring the pro- gram’s success, Ms. Katz emphasized that the Medication Grant Program, alone, does not prevent people from being rehospitalized or reincarcerated. “Having the medication grant card is very helpful, but it isn’t sufficient to address recidi- vism. The program is a piece of an effort to stop this [individuals cycling in and out of jail, prison, or the hospital],” she said.

For example, Ms. Katz pointed out that another piece of this effort is a provision in Kendra’s Law that provides funding to counties for jail-based case managers. “These managers help people who are being released from jail by linking them to community services, helping them to community services, helping them...”
al health information may be used or dis-
closed without specific patient, managed care
providers, or Medicare carriers and CERT contractors.

In addition, it is important to note that
HIPAA-compliant authorization and must include
specific details about the information to be released,
the name of the person receiving the information, and an expir-
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