When it comes to risk management, insurance executives and opioid treatment programs (OTPs) share a common goal: good outcomes for patients. But a good risk management and quality assurance program also means clinics need to carefully assess areas of risk to the patient, the OTP, and the community. Recently, the report of an extraordinarily high out-of-court settlement in which a Massachusetts OTP paid $1.8 million to the family of a child who died in an automobile crash caused by a patient, also killed in the accident, circulated like wildfire throughout the OTP community (see link to article on page 6). The patient was taking Klonopin (clonazepam) and trazodone, which are sedating, in addition to his prescribed methadone.

Two overriding trends in OTP claims involving adverse drug events are an increased frequency of reported incidents and claims, and an increased severity of outcomes and settlements.

To learn more about impaired driving and insurance-claim trends in OTPs, AT Forum spoke with Richard J. Willetts, CPCU, ARM, program director of the Addiction Treatment Providers Insurance Program of the NSM Insurance Group in Conshohocken, Pennsylvania.

Impaired-Driving Claims
“We are very concerned about impaired-driving exposure,” says Mr. Willetts, who represents liability-insurance companies. After wrongful death via adverse drug events, impaired driving is the most common type of claim against OTPs. Impaired-driving claims have increased in the past couple of years, something he attributes to the increase in attorney involvement in all methadone-related claims. “OTPs have become a target,” he says.

“It’s particularly important for OTPs to understand that the ramifications of not dealing with problems like driving will be worse than imposing restrictions on certain patients now,” says Mr. Willetts. “I understand they’re focused on their mission, which is helping patients, but if they don’t deal with this now, the potential is for public reaction to lead to something like banning methadone patients from driving.”

Under no circumstances think that “what you don’t know won’t hurt you.” It’s what you should know that counts—and how you act on that knowledge, says Mr. Willetts. Under well-established legal doctrine, health care providers are required to be aware of the potential for their patient to harm someone else. That’s where the impairment issue comes in. If a patient is impaired and you know the patient plans to drive, you should either defer dispensing the methadone or prevent the patient from taking the wheel, he says, acknowledging that this is the view of an insurance person, not a clinical person.

Staff, clinicians, and dosing nurses should be trained to identify impairment, notes the insurance executive. “Some don’t seem to pay as close attention as they
Patients in medication-assisted treatment (MAT) will not have their records disclosed without their consent, according to the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Office of the National Coordinator (ONC) for Health Information Technology. On June 16 the agencies released the Frequently Asked Questions (FAQs) for applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE), and ended debate about whether these regulations—known as 42 CFR Part 2—need to be changed in order to keep up with electronic health records.

Proponents of changing the regulations had argued that in order to deliver good health care, providers need to freely exchange information on whether patients are on methadone or have addiction problems. The FAQs, written by the Legal Action Center, show that the information can be exchanged with the patient’s consent.

Methadone Under Fire in Pennsylvania

Lawmakers in Pennsylvania are considering a package of bills that would severely restrict medication-assisted treatment (MAT) with methadone within the state. The most onerous provisions would require patients to have failed twice at drug-free treatment before admission, be tapered off methadone within one year of starting treatment, and use a designated driver for the first two weeks of treatment. Methadone advocates pointed out that the reasons for the package—dubbed by bill sponsors the “Methadone Accountability Package”—are based not in science, but rather in NIMBY-ism (referring to the “Not In My Backyard” doctrine).

“If something like this passes, it’s turning one tragedy into thousands of tragedies,” said George Woody, MD, professor of psychiatry at the University of Pennsylvania School of Medicine. “Methadone reduces the risk for overdose deaths. These bills are totally counter to the data.”

But Sen. Kim Ward is concerned about “open-ended treatment” and is calling for an audit of how much the state spends on methadone. “It doesn’t help to keep people on methadone for 10 years,” she told AT Forum.

She is also calling for the state to account for the money it spends on transporting patients to and from treatment.

Under Senate Resolution 348, passed in late June, the Legislative Budget and Finance Committee will conduct an audit to determine the annual cost of methadone treatment to Pennsylvania. The audit will study the length of treatment for each individual, and determine whether there is a plan for terminating methadone maintenance for each individual.

The best strategy would be to pass the bill authorizing a methadone incident review panel, suggested Mark Sarneso, legislative director for CRC, which has two methadone programs in Pennsylvania. “That would show that most of the incidents don’t have to do with clinics, but with pain prescriptions.”

See online version at ATForum.com for links to the proposals.

Court Ruling Supports Nurses on Methadone in Pennsylvania

A lawsuit charging that the Pennsylvania Board of Nursing has a secret policy banning nurses from being on methadone is allowed to go forward, a federal judge ruled in June.

The ruling said that the Americans with Disabilities Act (ADA) may make it illegal for Pennsylvania to require a nurse to be off methadone before obtaining or retaining a license, said U.S. District Judge James M. Munley in Reynolds v. Commonwealth of Pennsylvania. “Plaintiff has been forced to choose between abandoning a successful treatment for her addiction and ending her career as a nurse,” Judge Munley wrote.

The state does not admit that it won’t allow nurses on methadone to have a license, according to the lawsuit. Instead, it requires nurses who are addicted to opioids to go to a state-approved facility for treatment, and use a designated driver for the first two weeks of treatment. Methadone advocates pointed out that the reasons for the package—dubbed by bill sponsors the “Methadone Accountability Package”—are based not in science, but rather in NIMBY-ism (referring to the “Not In My Backyard” doctrine).

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See online version at ATForum.com for links to the proposals.
In 2003 Aegis Medical Systems resolved to develop a collaborative relationship with its patients, and those efforts culminated in the formation of the Patient Advisory and Advocacy Group (PAAG). Since then, the PAAG has consistently served as an informal venue allowing Aegis patients to give feedback to all levels of management—on both a local and corporate level—at the California-based network of opioid treatment programs (OTPs).

Just as significant has been the role the PAAG has played in numerous patients-rights causes. PAAG members have frequently testified before California State Assembly and Senate committees. On a local level, PAAG representatives have served as strong opponents of the stigma associated with methadone treatment in the communities that Aegis serves.

**Feedback on Policies**

One of the primary roles of the PAAG has been to provide a patient perspective to Aegis management on new and modified policies, protocols, and procedures. According to Aegis President and CEO Udi Barkai, “Periodic meetings are held between the PAAG board and Aegis corporate management. As a result, the PAAG has been quite influential. Feedback from the PAAG has become an essential part of our decision-making process. We truly could not get this perspective from any other source.”

A prime example of the PAAG’s influence relates to Aegis’ proposal to change some of the clinics’ hours to accommodate evening dosing. “Surprisingly, the proposal was ultimately nixed after the universally negative response from PAAG members,” says Mr. Barkai. “Although evening dosing would have been more convenient for clinic staff, not a single PAAG member was willing take part in a trial for the new schedule.” This informed Aegis management that patients, as a whole, would also be unlikely to welcome evening dosing hours.

PAAG members admitted to Aegis management that their reticence was due primarily to an unwillingness to stray from their established routine. They stated that patients were very set in their ways, and that receiving medication in the morning was so ingrained into their routine that a change would not be welcome. As a result, Aegis management withdrew its proposal, and decided it would be better not to jeopardize something that was already working well, Mr. Barkai tells AT Forum.

PAAG members have also provided advice on how to improve program services and amenities for patients, such as:

- Educational materials
- Contingency management guidelines
- Treatment programs for young patients
- Protocols for anger management, domestic violence intervention, and nutritional counseling

**Local PAAG Chapters**

Meetings between the local PAAG chapters and clinic managers are held in each of Aegis’ 25 clinics. Mr. Barkai shared that, “On the micro level, our clinic managers are simply able to make more-informed decisions on matters directly impacting patient lives, such as scope of services, scheduling, support groups, and vaccinations.”

The presence of the PAAG in each clinic helps counteract what can be a too-dominant or paternalistic position of clinicians, especially as the treatment field becomes more “consumer” oriented. Patients need a “sense of ownership of their recovery,” says Mr. Barkai. “This helps them feel invested in, and therefore actively participate in, getting better.”

**Advocacy to Fight Stigma and Discrimination**

The second role of the PAAG is advocacy and community relations work. “This work targets the stigma and discrimination associated with addiction recovery. In many ways, patients can be the strongest advocates in the political world. Participation of PAAG members allows decision makers to put a ‘face’ on the concept of treatment and recovery,” says Mr. Barkai.

In one instance, two members of the PAAG board testified before the California State Senate in support of a bill authorizing the use of buprenorphine in maintenance and detoxification programs. In another instance, the PAAG advocated before the State Assembly for legislation that required the Department of Corrections to provide medication-assisted treatment (MAT) within the prison system. The PAAG board members and local chapters have also been extremely successful in organizing petitions opposing reductions in the level of services and funding for MAT, adds Mr. Barkai.

“Feedback from the PAAG has become an essential part of our decision-making process.”

“In 2003 Aegis Medical Systems resolved to develop a collaborative relationship with its patients, and those efforts culminated in the formation of the Patient Advisory and Advocacy Group (PAAG). Since then, the PAAG has consistently served as an informal venue allowing Aegis patients to give feedback to all levels of management—on both a local and corporate level—at the California-based network of opioid treatment programs (OTPs).
Legislators and community leaders are more likely to heed testimony from patients than from treatment providers, but it’s usually very difficult to find methadone patients who are willing to come forward. The PAAG can give them the authority to feel more confident—and at the same time, boost the public relations of the OTP more than any manager could.

As it relates to community relations, local PAAG members have participated in a number of events, such as Recovery Happens and Red Ribbon rallies held throughout California. PAAG members also attend open houses and assist in presentations for local agencies, officials, and providers.

Other community relations and advocacy work done by the PAAG:

- Cultivating good relationships with neighbors, for example, by helping patients follow parking rules
- Contesting denial of medical services to active OTP maintenance patients
- Educating the general public, as well as governmental and medical establishments and representatives, including the Department of Social Services, parole and probation officers, judges, and physicians
- Sponsoring the California Parole and Probation Officer Annual Conference, and working with the local court system in other ways
- Implementing training in basic computer skills for patients

Therapeutic Effect For Members

How does Aegis choose patients to be on the PAAG? “We look for our best past and present patients who have long, successful histories of recovery,” says Mr. Barkai. “In particular, we are looking for patients with positive leadership qualities, as well as stable family and work lives.”

In addition to helping the OTP, patient advocates contribute to their own recovery by publicly supporting treatment. PAAG members feel positive about their ability to make a difference, and appreciate the chance to express themselves in the debate.

The Importance of Patient-Run Support Groups

Another important Aegis initiative the PAAG took part in was the creation of patient-run support groups, called Keys to Recovery (K2R). A great part of the growth of K2R is directly attributable to the efforts of PAAG members. K2R groups are similar to 12-step groups (and were originally called “Methadone Anonymous” by Aegis).

The PAAG advised Aegis management to make it mandatory that all new patients go to three K2R meetings. Originally not in favor of mandating attendance, Mr. Barkai changed his mind when the PAAG explained that once involved in the groups, patients would become more committed to recovery. Medication alone is not treatment, and patients need to “commit the time and effort required to work on their other issues. These groups allow patients to receive support from their peers, who have intimate knowledge of the common obstacles facing those working towards recovery,” Mr. Barkai explains.

The Future

“PAAG currently has more than 70 members throughout California,” says Mr. Barkai, “and we have recently begun developing specialized PAAG groups composed of young patients, family members of patients, and even groups focused on the cultural preferences of certain ethics groups within our patient population.

“The PAAG has come a long way since we had our first few members in 2003, and has already proved to be an invaluable source of inspiration to both our patients and staff,” says Mr. Barkai. “We believe that the PAAG will not only grow in significance as time passes, but that it can serve as an example for others in our industry of the possibilities of collaboration and the involvement of the patients in their treatment.”

For more information, visit the Aegis PAAG and Keys to Recovery websites at www.aegispaag.com and www.keys2recovery.com.

California Governor Proposes Cutting MAT

In May, Gov. Arnold Schwarzenegger proposed eliminating the entire Drug Medi-Cal (DMC) program except perinatal services. Total “savings” to the State General Fund proposed by virtual elimination of DMC, the only statewide funding for Medication-Assisted Treatment (MAT), is $53 million. Approximately 55 percent of patients enrolled in MAT use DMC to pay for their addiction treatment services.

The budget situation in California is worse than it is in many smaller states, but other states are also cutting back on addiction treatment. Now is the time, especially with the increase in prescription drug abuse, for OTPs to ramp up advocacy and make sure that their voices are heard in budget battles. As AT Forum went to press, it looked like a long, hot summer in for advocates in California.

For ongoing coverage of proposed Medi-Cal budget cuts visit www.savemedi-caldrugtreatment.org.
Liability and Insurance-Claim Trends

(continued from page 1)

should.” Other red flags in the Massachusetts case: the OTP violated its own policy on take-homes, and the patient missed counseling sessions. “Missing sessions may not seem like a big deal, but it’s a very big deal in court,” says Mr. Willetts. In addition, the patient had a lengthy history of motor vehicle accidents. “That’s important information that should have been collected during admission.”

There are no easy solutions to this problem. In many parts of the country, patients have to drive long distances to pick up their methadone, and have no other way to obtain it. The Massachusetts case is a wake-up call, and clinics should try to help prevent impaired driving.

As OTPs know, patients stabilized on their dose of methadone are usually not sedated or impaired by it, and can safely take therapeutic doses of benzodiazepines. But that doesn’t mean courts will agree with the science, says Mr. Willetts. “I hear it all the time—and I have 10 experts who can testify to that. But the person suing can get 10 experts who say the opposite.”

Many OTPs don’t like the idea of settling when they get a claim. “They say they didn’t do anything wrong, so why do they have to pay?” He has to explain to them that the end result would be much worse if a jury were in control. “If we don’t settle it for $300,000, a jury could award $3 million or much more. In 99 percent of these cases, settlement is out of court. Insurance companies rarely ever take these cases to trial.”

Claims Involving Adverse Drug Events

A growing concern for insurers is claims related to adverse events during methadone therapy. Two general issues result in increased scrutiny of OTPs.

- Statistically significant increases in the overall number of methadone-related deaths (including those involving pain clinics)
- Increasingly negative news articles and public information about OTPs and the safety of methadone

The Four Cs of Risk Management

There are four “C”s for OTPs to adhere to when it comes to managing risk, according to Mr. Willetts:

- Stay Current with scientific and clinical information about methadone and best practices. To do this, go to workshops, join the American Association for the Treatment of Opioid Dependence (AATOD), participate in training sessions.
- Collect patient information during treatment.
- Communicate with the family and patient. Explain all issues surrounding induction—the most risk-intensive phase—in particular.
- “Carefully document information on an event. You live and die with the documentation after an incident.”


Accessed June 21, 2010

Two overriding trends in OTP claims involving adverse drug events are an increased frequency of reported incidents and claims, and an increased severity of outcomes and settlements. As Mr. Willetts notes, many “hungry lawyers” use the internet to find plaintiffs, with impaired driving being one of the most significant new causes of action. And the greater the involvement of attorneys, the higher the claims costs.

Insurance-claim experience with OTPs and health care providers in general clearly shows that providing top quality and individualized clinical care is the best way to manage liability exposure.

Changing Insurance Market

Right now, the insurance market is “soft,” meaning that companies are scrambling to write policies, says Mr. Willetts. But the market is about to change. “Methadone clinics are what mortgage lenders would call subprime risks,” he says, adding that in the near future, readily available and adequate insurance will be difficult to find, as companies become more aware of claims like the Massachusetts settlement for $1.8 million.

The internet has drastically changed the environment for clinics, by whipping up anti-methadone sentiment and spawning many advertisements from lawyers. Ten years ago there was one incident a year per 100 clinics—now it’s three, says the insurance executive. And the average dollar-amount for each out-of-court settlement has doubled, from $150,000 to $300,000.

Mr. Willetts maintains that you can’t control the insurance-market cycle, but you can implement risk management strategies that make you a better risk, so when the market does change, you won’t have incidents on your record. “I see the potential for a clinic to have to close because it isn’t able to secure liability insurance.”

Insurance-claim experience with OTPs and health care providers in general clearly shows that providing top quality and individualized clinical care is the best way to manage liability exposure, Mr. Willetts stresses.

http://www.timesargus.com/article/20100410/NEWS/100419999/1003/NEWS02
Why Patients Leave Methadone Treatment Too Early

Patients who stay in methadone treatment for 12 months or longer have better therapeutic outcomes—yet most drop out within the critical first year. According to a recent study funded by the National Institute on Drug Abuse (NIDA), a major factor is a clinic’s views of its patients.

Clinics perceiving methadone patients as “consumers” who spend time and often money on treatment for opioid addiction generally try to attract patients by providing services such as child care, flexible hours, and help with housing and transportation. Clinics with the classic view of patients as “beneficiaries,” for whom treatment is considered a privilege, may offer patients fewer options and focus on the needs of the program rather than those of the patient. The authors suggest that by viewing patients as consumers of services, rather than beneficiaries, methadone clinics can retain patients in treatment longer and improve therapeutic outcomes.

Participants in the study were 42 patients prematurely discharged from six methadone programs in metropolitan Baltimore, Maryland. The study spanned 18 months, ending in June 2006, and was based on in-depth, semi-structured interviews. About 64 percent of participants were black, the remainder white. Average age of participants was 40 years. About 60 percent were men. Approximately 74 percent of participants reported injecting heroin. The average length of treatment was 124 days, and the group had an average of three prior drug-treatment episodes.

Except for incarceration, reasons for early discharge were program-related rather than patient-related.

Reasons for Premature Discharge

Of the 42 patients, 17 left early for program-related reasons, 16 because of incarceration, 5 in order to become free of all addictions, and 4 because of life events or logistics. The following discussion indicates the somewhat rigid “beneficiary” thread ran through patients’ dissatisfaction and departure.

Conflicting Views of Reasons for Discharge

Counselors had to select a reason for discharge from eight categories. “Left before completing treatment” was the counselors’ most common reason, even for incarcerated patients. According to the authors, this suggested unawareness of the true reasons, but an alternate explanation could be that staff do not necessarily consider paperwork to be related to treatment. Yet the discharge summary report can be important, because ideally it accompanies the patient to any subsequent programs, possibly influencing the patient’s later attempts at recovery.

Specific Program-Related Factors

- Disagreement with program rules. Some participants were frustrated with program policies and procedures that they believed were applied inconsistently or continuously changed, hindering their ability to improve their lives. For example, a homeless patient had a specific plan for regaining a construction job, but his counselor put other projects in his way, then complained he lacked stable housing. “So I was really bummed.” He left the program.

- Conflicts with staff. Some conflicts with counselors led to confrontations and discharge from the program. Program directors sometimes refused patients’ requests for a different counselor. Some patients saw counselors as disrespecting patients’ “street” education. A patient complained that he didn’t need anyone, because he was “a grown man.”

- “Feetox.” Rapid detoxification and discharge because of late payment or nonpayment of fees evoked strong reactions. “It’s all about money,” said an exasperated patient who was feetoxed after falling less than a week behind during the first month of treatment.

- Scheduling conflicts. Many patients tried to cope with schedules, public transportation problems, family obligations, and job-seeking. A “beneficiary” working a 12-hour shift couldn’t get to the clinic while it was open. Another found a good job, but the commute was an hour and a half. Both chose work over treatment. The authors did not comment on the possibility that without treatment, relapse and possible job loss might occur.

Desire to be Free of Addiction

Despite a generally positive view of methadone, more than 10 percent of discharged patients left treatment primarily to be free of all medication. Some were “scared of becoming dependent” on methadone. A patient said that trying to work and get to the clinic during the time the clinic was open “became like a schedule,” letting yet another drug—methadone—control his life.

(continued on page 8)

Methadone Treatment on Release From Prison
—It Works!

Prisoners started on methadone one month prior to release are more likely to be in treatment and heroin-free six months after release than prisoners who receive counseling alone, according to research funded by the National Institute on Drug Abuse (NIDA). Speaking at the Blending Conference in April, NIDA director Nora Volkow, MD called for this evidence-based treatment to be implemented throughout the country. “This is a win-win scenario,” said Dr. Volkow.

![Graph](image-url)

Treatment Linkage and Days of Heroin Use 6 Months Post-Release

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</table>

Source: Gordon, MS et al., Addiction 103:1333-1342, 2008
Why Patients Leave Methadone Treatment Too Early

(continued from page 7)

Discussion

The authors note that while studies indicate that the clinic director sets clinic policies, the counselor usually has to interpret and enforce the rules, which can create a conflict with their role as therapists. The authors believe that rules regarding take-home doses, missed doses, hours of operation, and children’s presence at the clinic may be critical factors in patient satisfaction and retention.

The authors identify several current problems:

- A short supply of methadone treatment in the Baltimore area, limiting patients’ choices and putting some in a dependent relationship with a program.
- Inability of some patients to negotiate clinic rules.
- Decreased funding for methadone programs over the years, increasing counselors’ case loads, making individualized attention difficult, and decreasing the variety of patient services.
- Financial pressures may lead to “feetoxing” patients. The authors note that data appear to refute the idea that contributing fees is “therapeutic,” even for indigent patients. Heroin-addicted individuals given free treatment are more likely to enter and remain in therapy than those required to pay.

Suggestions for Staff to Increase Retention

- Clearly explain program rules to patients
- Have an appeal system offering a patient advocate
- Allow patients to switch counselors if conflicts cannot be resolved
- Consider having clinical experts review each patient’s case before discharge
- Instruct counselors to document patients’ reasons for leaving treatment
- Separate counselors’ rule-enforcement and counseling functions

Study Limitations

Because of social desirability, or lack of insight, reasons patients gave may not be accurate. Moreover, elapsed time may have altered patients’ memory of events. Nevertheless, the data may help programs improve their approaches and their outcomes.