



Methadone Death & Incident Review

2013 Annual Report

Promoting Safety, Reducing Methadone-Related Deaths and Incidents and Improving Treatment Practices

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LEGISLATIVE MANDATES

The MDAIR team shall:

- Develop a form for the submission of methadone-related deaths and methadone-related incidents to the team by any concerned party. (P.L. 1198, No. 148 Cl. 35, Section 3 (d)(6))
- Develop, in consultation with a statewide association representing county coroners and medical examiners, a model form for county coroners and medical examiners to use to report and transmit information regarding methadone-related deaths to the team. The team and the statewide association representing county coroners and medical examiners shall collaborate to ensure that all methadone-related deaths are, to the fullest extent possible, identified by coroners and medical examiners. (Section 3 (d)(7))
- Develop and implement any other strategies that the MDAIR team identifies to ensure that the most complete collection of methadone-related death and methadone-related serious incident cases is created. (Section 3 (d)(8))
- Examine the circumstances surrounding methadone-related deaths and methadone-related incidents in the commonwealth for the purpose of promoting safety, reducing methadone-related deaths and incidents and improving treatment practices. (Section 3 (a))
- Determine the role that methadone played in each death and methadone-related incident. (Section 4 (d)(2))
- Communicate concerns to regulators and facilitate communication within the health care and legal systems about issues that could threaten health and public safety. (Section 4 (3))
- Develop best practices to prevent future methadone-related deaths and methadone-related incidents. The best practices shall be promulgated by the Department of Drug and Alcohol Programs (DDAP) as regulations and posted on its website. (Section 4 (4))

- Collect and store data on the number of methadone-related deaths and methadone-related incidents and provide a brief description of each death and incident. The aggregate statistics shall be posted on DDAP's website. The team may collect and store data concerning deaths and incidents related to other drugs used in opiate treatment. (Section 4 (5))
- Prepare an annual report that shall be posted on DDAP's website and distributed to the Chairman and Minority Chairman of the Judiciary Committee of the Senate, the Chairman and Minority Chairman of Public Health and Welfare Committee of the Senate, the Chairman and Minority Chairman of the Judiciary Committee of the House of Representatives and the Chairman and Minority Chairman of the Human Services Committee of the House of Representatives. Each report shall: provide public information regarding the number of causes of methadone-related deaths and incidents; provide aggregate data on a five-year trend on methadone-related deaths and incidents, when available; make recommendations to prevent future methadone-related deaths, methadone-related incidents and abuse and set forth the department's plan for implementing the recommendations; recommend changes to statutes and regulations to decrease methadone-related deaths and incidents; and, provide a report on methadone-related deaths and methadone-related incidents and concerns regarding narcotic treatment programs. (Section 4 (9))

ACKNOWLEDGEMENTS

To effectively prepare for the MDAIR team meetings and to assist with the team's review, Department of Drug and Alcohol Programs Secretary Tennis, pursuant to Section 8 (f) of the MDAIR Act, invited other stakeholder representatives and commonwealth employees to provide support to the team members as needed. Particular credit goes to Dr. Dale Adair, DPW Office of Mental Health and Substance Abuse Services; Dr. David Kelley, DPW Office of Medical Assistance Programs; Susan Shanaman, Esq., Legislative Liaison for the Pennsylvania Coroners Association, for her many valuable contributions to the effectiveness of our information gathering process; as well as to Michele Denk, Executive Director for the Pennsylvania County Drug and Alcohol Directors Association.

Secretary Tennis would like to give *special* thanks to the following DDAP Bureau of Quality Assurance for Treatment and Prevention and other DDAP staff members; without their efforts that went beyond the call of duty, this important work could not have been completed:

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Letter from the Secretary

Drug and alcohol addiction is a disease that afflicts one out of four families in Pennsylvania and across the nation. Although most Pennsylvanians suffering with addiction are still in the workplace and are not involved in our criminal justice system, over 70 percent of those who *are* incarcerated are there with untreated addiction. Meanwhile, as a nation, we continue to struggle to identify ways to fund necessary and appropriate drug and alcohol treatment for those individuals suffering from addiction. We must realize that there are far greater costs being borne by our communities when individuals are unable to access or afford necessary drug and alcohol treatment.

In the context of appropriate treatment, it is clear that methadone-assisted treatment serves as one of the essential modalities for those suffering from opioid (heroin and prescription opioid) addiction. In this first year of our Methadone Death and Incident Review team, fatal opioid overdoses in Pennsylvania have reached tragically unprecedented levels. Heroin in particular is prevalent in communities that have until now never dealt with it. It continues to be true that receiving appropriate treatment – whether it is medication-assisted or drug-free – is life-saving. We need the full diversity of treatment options, including methadone-assisted treatment; if we provide sufficient resources to empower our treatment providers to do their jobs with clinical integrity, those who today are at risk of death from addiction can gain their recovery and go on to become responsible, contributing individuals with the richness and fullness of life to which millions of recovering individuals can attest.

Pennsylvania has seen an increasing number of reports of cases where individuals have overdosed on methadone or on methadone combined with benzodiazepines or other drugs, and as with many other medicines, if not these drugs are not administered and used with care serious harm or even death can occur. Indeed, the Center for Disease Control (CDC) reports that methadone overdose deaths increased six-fold between 1999 and 2009. As a result, within months of its creation, the Department of Drug and Alcohol Programs (DDAP), on its own initiative joined forces with Department of Public Welfare Medical Directors to begin an informal process of reviewing methadone deaths. A few months after that initiative began, the General Assembly passed, and Governor Corbett signed into law, Act 148 of 2012, the law formalizing the Methadone Death and Incident Review team and calling for this annual report.

I am deeply grateful to the members of the MDAIR team for their tireless participation and engagement in our many lengthy meetings. With strong (though short-handed) DDAP staff support, we have laid down the framework in which methadone-related deaths and incidents can be reviewed, although we still have far to go in determining how to gather information on methadone-related deaths and incidents in the context of pain management. Perhaps most

importantly, we have developed an effective process from which recommendations can be drawn to make methadone treatment practice safer and more effective.

And that is our aim: to make the use of methadone in addiction treatment as safe and as effective as it can be. The recommendations below reflect that aim. Going forward in 2014, the MDAIR team's biggest challenge is to determine how to effectively gather cases in which methadone is used in *pain management*. In that context, the CDC reports that while methadone is used in about two percent of painkiller prescriptions in the United States, it is responsible for over 30 percent of fatal prescription overdoses – it is imperative that we be able to gather those cases as well.

Nonetheless, the MDAIR team, based on the review of the cases before it, has arrived at a substantial number of substantive recommendations to improve the safety and effectiveness of methadone practice. For the most part, implementation of those recommendations will fall upon DDAP, either through regulation change or other practice change. We believe that implementation of those recommendations will indeed save lives, thus forwarding the enlightened purpose of the General Assembly and the Governor in enacting Act 148.

Sincerely,

A handwritten signature in blue ink, appearing to read "Gary Tennis", with a stylized flourish extending to the right.

Gary Tennis
Secretary
Department of Drug and Alcohol Programs

INTRODUCTION

The Methadone Death and Incident Review Act (MDAIR Act; Act 148) was enacted on October 24, 2012 (see Appendix A). Pursuant to the MDAIR Act, the designated purpose of this legislation is to examine the circumstances surrounding deaths and incidents in Pennsylvania that involve or may involve methadone. The Methadone Death and Incident Review (MDAIR) team has been established to review the cases that fall within the purview of the statute. By legislation, the team membership is comprised of:

1. Secretary of the Department of Drug and Alcohol Programs (DDAP) or a designee
2. Director of the Bureau of Treatment, Prevention and Intervention (Director of Bureau of Drug and Alcohol Programs-as per legislation)
3. A representative from a narcotic treatment program
4. A representative from a licensed drug and alcohol addiction treatment program that is not a narcotic treatment program
5. A representative from law enforcement
6. A representative from the medical community
7. A district attorney
8. A coroner or medical examiner
9. A member of the public
10. A patient or family advocate

Members of the MDAIR team meet regularly to review cases involving deaths and incidents that are purported to involve methadone and to work toward appropriate recommendations based on that review. These cases are prepared and presented to the team by DDAP staff. Information is provided by coroners, private citizens, methadone clinics, and police departments. DDAP staff investigate the information submitted, utilize all available resources, and provide factual reports to the team based on the available information. In order to compile information, staff request and review, as appropriate, coroners' reports, death certificates, law enforcement records, medical records, children and youth reports, court records, traffic reports, narcotic treatment program incident reports and facility records, family records, Department of Public Welfare information and reports, and media information. In reviewing the cases, the MDAIR team has the following objectives:

1. Review cases involving deaths and incidents where methadone was the primary, secondary or contributing cause of death or incidents.
2. Determine the role that methadone played in each methadone-related death and incident.
3. Communicate concerns to regulators and facilitate communication within the healthcare and legal systems about issues that could threaten health and public safety.

4. Develop best practices and regulations to reduce future methadone-related deaths and methadone-related incidents; this endeavor is meant to inform regulatory change to be promulgated by DDAP.

We have conducted six MDAIR team meetings in 2013, all chaired by the Secretary of DDAP. In accordance with Act 148, the meetings are not open to the public, and any proceedings, deliberations and records are confidential and not subject to the Right-to-Know Law. However, any person with information relevant to the review may be invited to attend and provide information at a meeting.

Upon completion of the discussion, the team makes determinations about each case and, where appropriate, recommendations regarding what steps that can be taken to prevent, or at least reduce the likelihood of similar incidents in the future.

Confidentiality is maintained by team members and information presented to the team does not include the full names; moreover, the information presented at the meetings does not leave the meeting area. Finally, team members also sign an agreement not to share information outside of the team meeting.

Following preliminary planning, the first official MDAIR team meeting took place on April 1, 2013, with subsequent meetings thereafter. During these meetings, cases involving methadone deaths and incidents have been reviewed and recommendations made in an effort to identify areas to improve or enhance services and safety.

COLLECTION OF INFORMATION

In the MDAIR team's inaugural year, a considerable amount of information has been amassed. We have been on a learning curve in terms of gathering and processing the information in the most effective way. At inception, the development of a process for the compiling of information has been nuanced through trial and error and team recommendations. With respect to the use of methadone in the context of pain management, we continue to face formidable challenges in gathering complete information in apparent methadone death and incident situations.

The team has met regularly to review and refine this information gathering process, as well as reviewing the cases themselves. This process has led to the dissemination of information and the development of a format for processing this information. Team members have brought expertise, enthusiasm, dedication and a great deal of time and effort to the process; the outcome to date has been productive.

Information for the purpose of MDAIR team review is received through various sources and methods:

- Coroners provide information on a form jointly developed by the MDAIR team and the Pennsylvania State Coroners Association. Again, the Pennsylvania State Coroners Association has played a critical role in the effective execution of our mission.
- The current licensing regulations, in accordance with 28 Pa. Code Chapter 715, require that narcotic treatment facilities provide information to identify a patient death or incident. They also report on injuries and deaths sustained through the actions of a methadone patient. A report is completed that includes documentation pertaining to the treatment experience, medications administered, and any other information pertinent to the death or incident.
- The public is also encouraged to provide information. The DDAP website provides a reporting form for anyone to use to report an incident or death.
- MDAIR investigations rely on information from entities such as Police Chiefs, County District Attorneys, Pennsylvania's Child Death Review Team, Pennsylvania State Police and county drug and alcohol agencies, all of whom have been solicited by the DDAP Secretary as sources of critical information. By seeking multiple sources of information, the MDAIR team is working to ensure that we receive the maximum amount of relevant information for each case.

DDAP PROCESS AND RESOURCES

The staff from DDAP's Bureau of Quality Assurance for Prevention and Treatment developed a process in close collaboration with the MDAIR team to review and investigate methadone-related deaths and incidents. The MDAIR team utilized the services and expertise of these DDAP staff to complete its investigations. The assigned DDAP staff conducted the MDAIR investigations, working collaboratively with the coroners/medical examiners, police, narcotic treatment providers, pain management clinics and medical providers to gather information. This labor intensive task was initially spearheaded by two staff from the bureau, Deborah Graeff and Jocelyn Merriweather. Due to the increase in reporting and the time commitment required to complete each investigation, assignment of additional bureau staff became necessary. As a result, there are currently six staffers from the bureau who have been assigned to complete MDAIR investigations, in addition to their regularly assigned job duties.

The MDAIR Act allocated no funding for additional personnel or operating costs associated with the MDAIR process, which requires DDAP to utilize existing agency staff. If DDAP is expected to fulfil the full scope of MDAIR associated responsibilities, we estimate that it will require three full-time positions with additional staff in the future should we continue toward the goal of receiving comprehensive reporting from pain management clinics and private physicians who prescribe methadone. DDAP recognizes the critical nature of this initiative and will continue to devote existing resources, as needed, to fulfill the mandates of the Act until such a time that additional resources become available.

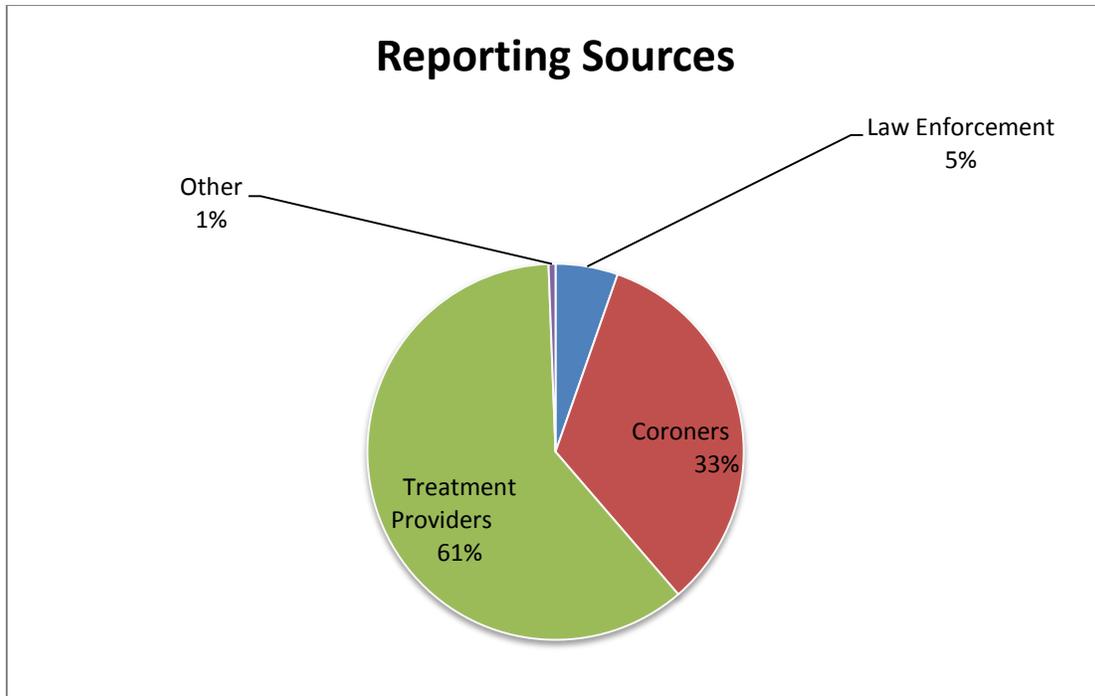
FINDINGS

2013 Methadone-Related Deaths and Incidents

During the inaugural year, the department received 146 reported cases relating to incidents and deaths in Pennsylvania where methadone was involved. After thorough investigation by DDAP Bureau of Quality Assurance for Prevention and Treatment staff, it was determined that in 30 of those cases, methadone was not a cause or contributing factor in the deaths and incidents. These 30 cases were not presented to the MDAIR team for review and evaluation. One hundred-sixteen of the cases received in 2013 were considered to be appropriate for further investigation and eventual referral to the MDAIR team for review and evaluation. Because it takes a good deal of staff time and investigation to have a case fully prepared for team review, just 16 of those cases were fully investigated and reviewed by the MDAIR team during 2013. The team found that methadone was not a cause or contributing factor in six of those 16 cases. Methadone was a cause or contributing factor in the other ten cases. We note that, in some cases where multi-drug toxicity was identified as a cause of death or incident, while methadone may have contributed to the fatality or episode, any of the other substances ingested by the individual may have been present in quantities sufficient to be impairing or lethal.

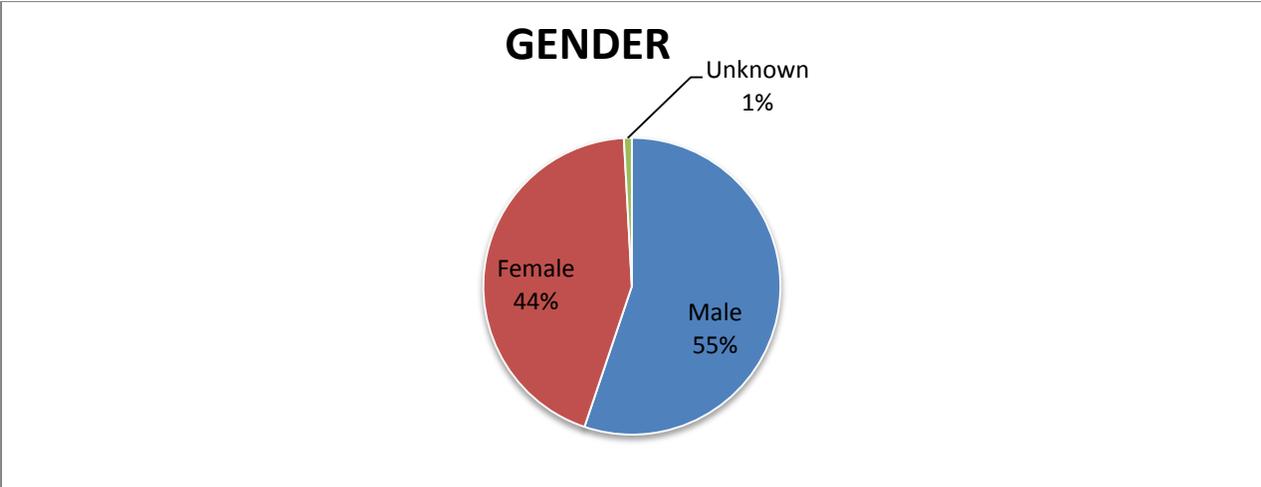
As of the date of this report, investigations have been completed by bureau staff on 25 other cases which are pending review by the MDAIR team. The remaining 75 cases are in various stages of review and investigation by bureau staff and upon completion of the investigations, will be presented to the MDAIR team for review and evaluation.

* The inaugural year provided a limited number of cases that had been reviewed by the MDAIR team. The statistical information that is included in this report should not be viewed as significant findings; however, the report is reflective of the work that has been completed and the ongoing development of the investigative process.

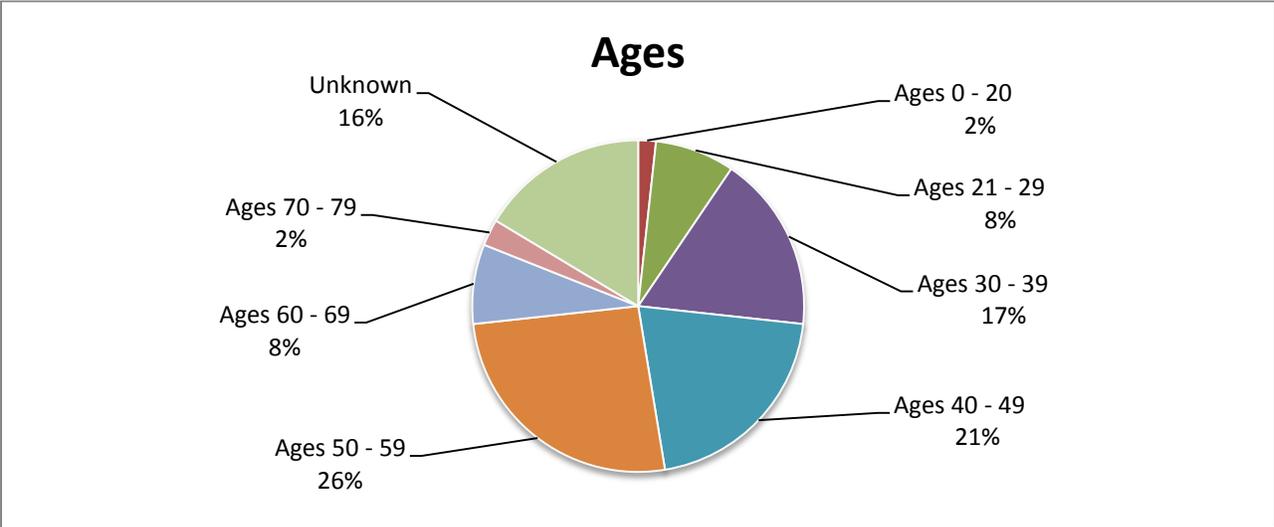


The MDAIR team partnered with statewide stakeholders to complete the methadone-related death and incident investigations. Information was obtained from coroners, medical examiners, local and state police, narcotic treatment providers, pain management clinics and medical providers. The majority of these reported incidents and deaths were submitted by Narcotic Treatment Programs (NTPs). By regulation, NTPs are required to submit unusual incident reports to DDAP. In addition, for the MDAIR process, the MDAIR treatment provider form was created for narcotic treatment providers. The pie chart above represents 167 reports DDAP received pertaining to the 146 cases for MDAIR consideration. These reports helped to initiate the investigative process. The NTPs have submitted 102 reports. The coroners and medical examiners offices have also been a critical source of information by submitting 56 MDAIR coroner reports. State and local police submitted nine reports.

DEMOGRAPHICS



One hundred-sixteen of the cases received were considered to be appropriate for further investigation. Of the reported methadone-related cases, 51 involved females and 64 were male.

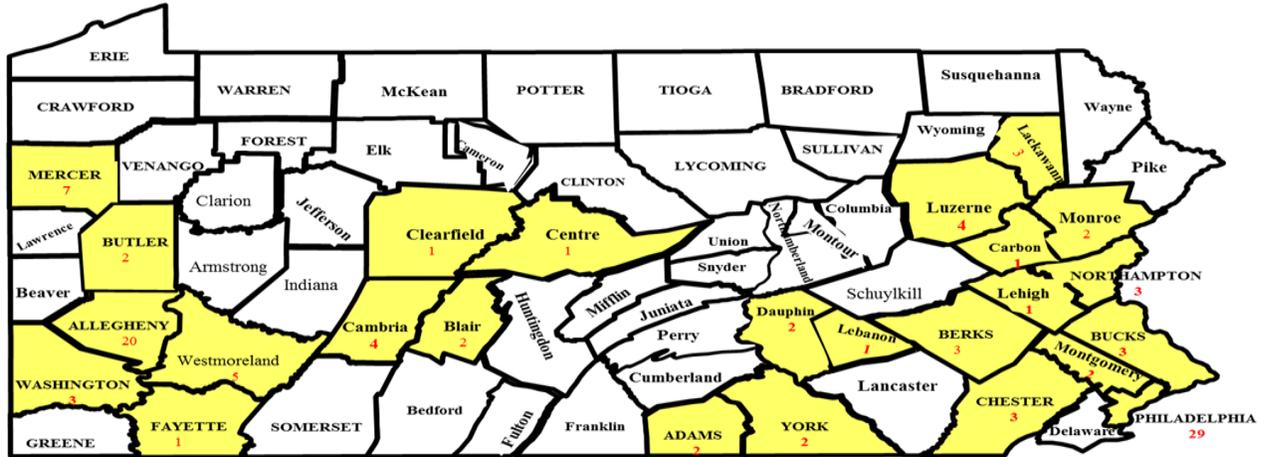


The above chart displays the ages that were reported. The youngest person was 17 years old and the eldest was 70. Investigations are still pending and the age is not yet known in every case.

Ages 0 – 20	2	Ages 50 – 59	30
Ages 21 – 29	9	Ages 60 – 69	9
Ages 30 – 39	20	Ages 70 – 79	3
Ages 40 – 49	24	Unknown	19

The map below reflects counties in which reports of methadone-related deaths or incidents occurred. The MDAIR team is working diligently to educate reporting entities on the value of supplying data. The team will continue to cultivate partnerships in order to reflect statewide occurrences of methadone-related deaths and incidents.

Counties



Adams 1	Centre 1	Luzerne 4	York 2
Allegheny 20	Chester 3	Mercer 7	
Berks 3	Clearfield 1	Monroe 2	Unknown 10
Blair 2	Dauphin 2	Montgomery 2	
Bucks 3	Fayette 1	Northampton 3	
Butler 2	Lackawanna 3	Philadelphia 29	
Cambria 4	Lebanon 1	Washington 3	
Carbon 1	Lehigh 1	Westmoreland 5	

RECOMMENDATIONS

As a result of MDAIR team meetings and the review of deaths and incidents involving methadone, the following recommendations were made. We recognize that these recommendations are based upon review of a relatively small number of cases; the MDAIR team, after review of cases in 2014, may choose to modify some of these recommendations:

A. General Recommendations:

1. Mandatory toxicology screens shall be performed on deaths where methadone appears to have been involved. (Recommendation made on 4/1/13)
2. There shall be a centralized location where the coroners could submit the form. (Recommendation made on 4/1/13, accomplished and ongoing)
3. Physician participants of the MDAIR team are encouraged to share an opinion on toxicology reports and to offer clinically appropriate recommendations. (Recommendation made on 5/27/14)
4. The team reviewed cases in which a forensic autopsy was not performed, though forensic toxicology was completed. Performing both forensic autopsies and toxicology screenings are important in determining cause and manner of death; however, performing both creates a significant cost to counties which they cannot afford due to budget restraints. The MDAIR team supports the Pennsylvania State Coroners Association's intended request for legislation to change the statutes to enhance the quantitative and qualitative analyses of the coroner's office. (Recommendation made on 9/9/13)
5. There shall be sanctions imposed on narcotic treatment facilities, including reasonable fines and license revocations, for those facilities that receive second or third provisional license. These fines will stay with the department. (Recommendation made on 9/9/13)

B. Recommendations for Narcotic Treatment Providers:

1. Induction Phase:

- A. Admission urinalysis testing shall occur no more than five days prior to induction.
- B. Drug history and personal history shall include documentation of prior treatment experience and outcome. Previous methadone treatment outcomes shall be reviewed as part of the assessment. The physician, in consultation with medical and clinical staff, will document an assessment that will identify the appropriateness of methadone treatment.

- C. Random urinalysis should be conducted at least weekly during the first three months of treatment and at least three months after the last positive urine.
- D. The current regulations shall be modified to indicate that the DDAP Bureau of Quality Assurance for Treatment and Prevention, Division of Program Licensure, where appropriate to protect patient safety, will be empowered to require that all dose adjustments during the induction phase be determined by a face-to-face consultation with a physician. The patient record shall include documentation of assessment and consultation by physician. The team will carefully review case practice to ensure that the induction phase is done safely.
- E. The patient will be recommended not to operate a motor vehicle during the first two weeks of treatment unless there is documentation by the physician that the patient is stable and able to operate the vehicle safely. If the Narcotic Treatment Program (NTP) physician concludes that a patient is not safe to drive, in accordance with current statutory requirements, he/she will report the patient to the Pennsylvania Department of Transportation (the MDAIR team will continue to review this issue).
- F. New patients will be provided an orientation to narcotic treatment that will include signs and symptoms of overdose, contraindications, use of other drugs and medications, and expectations for participation in treatment. The format for this orientation will include educational group sessions and individual education. The information provided during the orientation process shall be included in the patient handbook for reference.
- G. New patients will be encouraged to identify and include a family member, friend or sponsor in the induction process. Education sessions and materials shall be made available to the patient's support person. Efforts will be made to encourage a patient to sign a release of information to permit this contact with family members, friends or sponsors.
- H. New patients will meet for their first counseling session within 48 hours of admission. During the first six months of treatment, a patient shall receive weekly individual therapeutic counseling; the duration to be at least one hour.
- I. Following six months of methadone treatment, a patient will be assessed by the physician and treatment staff. Documentation of this assessment will identify if the patient should continue to be seen weekly for therapy or reduced to no less than two and a half hours of therapy per month as identified in the regulations.
- J. NTPs, in accordance with licensure regulations, shall develop a protocol for the induction phase of patient treatment in a narcotic treatment center.
(Recommendation made on 11/4/13)

2. Ongoing Treatment Practices:

- A. After several positive urine screens, a protocol shall be in place to increase the number of urine screens and therapeutic treatment. The MDAIR team recommends that DDAP shall do further work to identify best practices where clients being treated have positive urine screens or where clients are failing to engage in the therapeutic treatment regimen. DDAP shall develop best practices in order to re-engage patients who miss three consecutive days from treatment or who have positive urine screens.
- B. Physicians should follow medical best practices when determining dose changes for patients which shall include, but not be limited to best practices for dosing guidelines.
- C. Initial and ongoing training for practitioners in methadone or pain clinic settings shall consist of a minimum of 12 hours in two years specific to opiate prescribing, where available, with an emphasis on content specific to methadone treatment and addiction screening. (Recommendation made on 11/4/13)

3. Utilization of Benzodiazepines:

- A. NTPs will generally accept into methadone treatment all persons otherwise eligible for methadone treatment who are using properly prescribed benzodiazepines. Exceptions may be made in the case of persons known to have a history of recent or repeated benzodiazepines overdose.
- B. Non-approved use of benzodiazepines will be regarded the same as other illicit drug use except that time frames for cessation of use may be longer due to recommended detox considerations.
- C. Benzodiazepines shall be properly prescribed by a board eligible psychiatrist or an American Society of Addiction Medicine (ASAM) approved physician. The patient must also keep appointments with the prescribing physician and have the permission of the Methadone Maintenance Treatment medical director.
- D. The patient must not have had a benzodiazepine-related episode of overdose in the past five years.
- E. The patient must provide ongoing consent for NTP staff to contact the prescribing psychiatrist or addiction physician.
- F. The patient at no time subsequent to approval may be found to be using non-prescribed benzodiazepines or to present with sedation due to benzodiazepine use.
- G. NTP medical staff will contact the prescriber (referred to above) to discuss issues around co-medication. These will include dosage, type of benzodiazepine, length of benzodiazepine treatment, and other pertinent

issues. The patient's progress in the NTP will periodically be communicated to the benzodiazepine prescriber as well.

- H. The NTP will provide education to all new patients regarding the risks of co-medication of methadone and benzodiazepines, the limited use of benzodiazepines in treating mental health problems, and the program's policy regarding benzodiazepine use. When feasible, benzodiazepine-specific group counseling, on-site detox, referral for inpatient detox, and other support will be provided to both new and existing patients.
- I. In addition to the general Urine Drug Screen (UDS) and benzodiazepine screen, where appropriate, the NTP program may periodically utilize special laboratory tests to determine which benzodiazepine drugs are being taken by benzodiazepine-positive patients. This will include patients with approval to take benzodiazepine medication.
- J. NTP dosing staff will be kept informed of all patients whose most recent UDS was positive for benzodiazepines and will be consistently alert regarding such patients for signs of benzodiazepine toxicity or sedation. Patients exhibiting such signs will not be medicated and the medical director and clinical supervisor will be alerted.
- K. NTP programs will develop protocols acceptable to the department around the issues of management of benzodiazepine-impaired patients. These will include methadone dose issues, inpatient referral, termination of treatment, and other determinations relating to the safety of the patient.
- L. Where benzodiazepine-positive patients are not already approved for benzodiazepine medications but claim a need for such medication, the NTP program will provide a mental health assessment and, where appropriate, will arrange for a psychiatric evaluation which should take into consideration the individual's addiction.
- M. Except where the department provides an 'exception' in writing, NTP programs will include a portion of the required physician/certified registered nurse practitioner (CRNP) hours under Chapter 715 as on-site psychiatrist/psychiatric CRNP hours.
- N. NTPs should perform urinalysis drug screening for benzodiazepines on a regular basis.
- O. Patients using illicit drugs should be tested weekly.
- P. NTPs should be required to have a psychiatrist on staff to address mental health issues and benzodiazepine use among patients. (Recommendation made on 9/9/13)
- Q. Patients who are using benzodiazepines should not be allowed methadone take-home privileges. (Recommendation made on 9/9/13)

- R. NTPs should recommend alternatives to benzodiazepine to their patients.
(Recommendation made on 11/4/13)

C. Recommendations for Methadone Pain Management:

1. Initial and ongoing training for practitioners in methadone or pain clinic settings shall consist of a minimum of 12 hours in two years specific to opiate prescribing, where available, with an emphasis on content specific to methadone treatment and addiction screening. (Recommendation made on 05/27/14)
2. DDAP should recommend that appropriate state agencies improve regulatory oversight of providers prescribing methadone for pain management.
(Recommendation made on 11/4/13)
3. Recommendations for the Department of State and other agencies:
 - a. The Department of State, Pennsylvania Attorney General, Board of Medicine and Drug Enforcement Agency shall be asked to investigate the practices of providers whose patients may have overdosed and/or died where methadone was prescribed for pain management. (Recommendation made on 11/4/13)
 - b. The Department of State shall provide any information required by the MDAIR team to carry out the statutory obligations under Act 148.
4. Urine screening and physical exams should be conducted before prescribing methadone for pain management. (Recommendation made on 11/4/13)
5. Any person prescribing or dispensing methadone for pain management only shall identify the medication in the Prescription Monitoring Program (PMP). The team shall also continue to explore avenues to report information in the PMP in accordance with 42 CFR and other state confidentiality regulations.
(Recommendation made on 11/4/13)

APPENDIX A

MDAIR ACT (Act 148 of 2012)

METHADONE DEATH AND INCIDENT REVIEW ACT - ENACTMENT
Act of Oct. 24, 2012, P.L. 1198, No. 148 **Cl. 35**

An Act

Establishing the Methadone Death and Incident Review Team and providing for its powers and duties; and imposing a penalty.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Short title.

This act shall be known and may be cited as the Methadone Death and Incident Review Act.

Section 2. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Department." The Department of Drug and Alcohol Programs of the Commonwealth.

"Methadone-related death." A death where methadone was:

- (1) a primary or secondary cause of death; or
- (2) may have been a contributing factor.

"Methadone-related incident." A situation where methadone may be a contributing factor which:

- (1) does not involve a fatality; and
- (2) involves:
 - (i) a serious injury; or
 - (ii) unreasonable risk of death or serious injury.

"Narcotic treatment program." A program licensed and approved by the Department of Drug and Alcohol Programs for chronic opiate drug users that administers or dispenses agents under a narcotic treatment physician's order, either for detoxification purposes or for maintenance.

"Secretary." The Secretary of Drug and Alcohol Programs of the Commonwealth.

"Team." The Methadone Death and Incident Review Team established under section 3.

Section 3. Establishment of Methadone Death and Incident Review Team.

(a) Team established.--The department shall establish a Methadone Death and Incident Review Team and conduct a review and shall examine the circumstances surrounding methadone-related deaths and methadone-related incidents in this Commonwealth for the purpose of promoting safety, reducing methadone-related deaths and methadone-related incidents and improving treatment practices.

(b) Composition.--The team shall consist of the following individuals:

- (1) The secretary or a designee, who shall serve as the chairperson of the team.
- (2) The Director of the Bureau of Drug and Alcohol Programs.
- (3) The following individuals appointed by the secretary:

- (i) A representative from narcotic treatment programs as defined in 28 Pa. Code § 701.1 (relating to definitions).
- (ii) A representative from a licensed drug and alcohol addiction treatment program that is not defined as a narcotic treatment program.
- (iii) A representative from law enforcement recommended by a Statewide association representing members of law enforcement.
- (iv) A representative from the medical community recommended by a Statewide association representing physicians.
- (v) A district attorney recommended by a Statewide association representing district attorneys.
- (vi) A coroner or medical examiner recommended by a Statewide association representing county coroners and medical examiners.
- (vii) A member of the public.
- (viii) A patient or family advocate.

(c) Initial meeting.--The initial meeting of the team shall take place within 90 days of the effective date of this section. During this initial meeting, the team shall develop a schedule for its work and reports.

(d) Expenses.--Members of the team shall not receive compensation but shall be reimbursed for necessary travel and other reasonable expenses incurred in connection with the performance of their duties as members. If possible, the team shall utilize the services and expertise of existing personnel and staff of State government.

Section 4. Team duties.

The team shall:

- (1) Review each death where methadone was either the primary or a secondary cause of death and review methadone-related incidents.
- (2) Determine the role that methadone played in each death and methadone-related incident.
- (3) Communicate concerns to regulators and facilitate communication within the health care and legal systems about issues that could threaten health and public safety.
- (4) Develop best practices to prevent future methadone-related deaths and methadone-related incidents. The best practices shall be:
 - (i) Promulgated by the department as regulations.
 - (ii) Posted on the department's Internet website.
- (5) Collect and store data on the number of methadone-related deaths and methadone-related incidents and provide a brief description of each death and incident. The aggregate statistics shall be posted on the department's Internet website. The team may collect and store data concerning deaths and incidents related to other drugs used in opiate treatment.
- (6) Develop a form for the submission of methadone-related deaths and methadone-related incidents to the team by any concerned party.
- (7) Develop, in consultation with a Statewide association representing county coroners and medical examiners, a model form for county coroners and medical examiners to use to report and transmit information regarding methadone-related deaths to the team. The team and the Statewide association representing county coroners and medical examiners shall collaborate to ensure that all methadone-related deaths are, to the fullest extent possible, identified by coroners and medical examiners.
- (8) Develop and implement any other strategies that the team identifies to ensure that the most complete collection of methadone-related death and methadone-related serious incident cases reasonably possible is created.
- (9) Prepare an annual report that shall be posted on the department's Internet website and distributed to the chairman and minority chairman of the Judiciary Committee of the Senate, the chairman and minority chairman

of the Public Health and Welfare Committee of the Senate, the chairman and minority chairman of the Judiciary Committee of the House of Representatives and the chairman and minority chairman of the Human Services Committee of the House of Representatives. Each report shall:

(i) Provide public information regarding the number and causes of methadone-related deaths and methadone-related incidents.

(ii) Provide aggregate data on five-year trends on methadone-related deaths and methadone-related incidents when such information is available.

(iii) Make recommendations to prevent future methadone-related deaths, methadone-related incidents and abuse and set forth the department's plan for implementing the recommendations.

(iv) Recommend changes to statutes and regulations to decrease methadone-related deaths and methadone-related incidents.

(v) Provide a report on methadone-related deaths and methadone-related incidents and concerns regarding narcotic treatment programs.

(10) Develop and publish on the department's Internet website a list of meetings for each year.

Section 5. Duties of coroner and medical examiner.

A county coroner or medical examiner shall forward all methadone-related death cases to the team for review. The county coroner and medical examiner shall use the model form developed by the team to transmit the data.

Section 6. Review procedures.

The team may review the following information:

(1) Coroner's reports or postmortem examination records unless otherwise prohibited by Federal or State laws, regulations or court decisions.

(2) Death certificates and birth certificates.

(3) Law enforcement records and interviews with law enforcement officials as long as the release of such records will not jeopardize an ongoing criminal investigation or proceeding.

(4) Medical records from hospitals, other health care providers and narcotic treatment programs.

(5) Information and reports made available by the county children and youth agency in accordance with 23 Pa.C.S. Ch. 63 (relating to child protective services).

(6) Information made available by firefighters or emergency services personnel.

(7) Reports and records made available by the court to the extent permitted by law or court rule.

(8) EMS records.

(9) Traffic fatality reports.

(10) Narcotic treatment program incident reports.

(11) Narcotic treatment program licensure surveys from the program licensure division.

(12) Any other records necessary to conduct the review.

Section 7. Access to records.

(a) Juvenile records.--When deemed necessary for its review, the team may review and inspect all files and records of the court relating to a child pursuant to a proceeding under 42 Pa.C.S. Ch. 63 (relating to juvenile matters) in accordance with 42 Pa.C.S. § 6307 (relating to inspection of court files and records). This subsection shall not apply to files and records of the court subject to a child fatality or near fatality review pursuant to 23 Pa.C.S. Ch. 63 (relating to child protective services).

(b) Medical records.--Notwithstanding any other provision of law and consistent with the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191, 110 Stat. 1936) and 42 CFR Pt. 2 (relating to

confidentiality of alcohol and drug abuse patient records), health care facilities and health care providers shall provide medical records of an individual under review without the authorization of a person of interest to the team for purposes of review under this act.

(c) Other records.--Other records pertaining to the individual under review for the purposes of this act shall be open to inspection as permitted by law.

Section 8. Confidentiality.

(a) Maintenance.--The team shall maintain the confidentiality of any identifying information obtained relating to the death of an individual or adverse incidents regarding methadone, including the name of the individual, guardians, family members, caretakers or alleged or suspected perpetrators of abuse, neglect or a criminal act.

(b) Agreement.--Each member of the team and any person appearing before the team shall sign a confidentiality agreement applicable to all proceedings and reviews conducted by the team.

(c) Liability.--An individual or agency that in good faith provides information or records to the team shall not be subject to civil or criminal liability as a result of providing the information or record.

(d) Discovery.--The proceedings, deliberations and records of the team are privileged and confidential and shall not be subject to the act of February 14, 2008 (P.L.6, No.3), known as the Right-to-Know Law, discovery, subpoena or introduction into evidence in any civil or criminal action.

(e) Meetings.--Meetings of the team at which a specific death is discussed shall be closed to the public and shall not be subject to the provisions of 65 Pa.C.S. Ch. 7 (relating to open meetings).

(f) Attendance.--Nothing in this act shall prevent the team from allowing the attendance of a person with information relevant to a review at a methadone death and incident team review meeting.

(g) Penalty.--A person who violates the provisions of this section commits a misdemeanor of the third degree.

Section 9. Regulations.

The department shall promulgate regulations as necessary to carry out the purposes of this act.

Section 20. Effective date.

This act shall take effect in 90 days.

APPENDIX B

MDAIR CORONERS REPORT



DDAP-FM-0001
Rev. 03/05/2014

CORONER'S DRUG DEATH REPORT

This form should be submitted within 7 days of the completion of cause and manner of death.

Coroner's Name: [Click here to enter text.](#) **County:** [Click here to enter text.](#)

Date of Death: [Click here to enter a date.](#) **Time of Death:** [Click here to enter text.](#)

Coroner's Case #: [Click here to enter text.](#)

Manner of Death: [Choose an item.](#)

Cause of Death: [Click here to enter text.](#)

Was prescription medication or illicit drug a cause or contributing factor in the death? Yes No

Was methadone a cause or contributing factor in the death? Yes No

Was law enforcement involved? Yes No

If yes, what agency? [Click here to enter text.](#)

Contact person: [Click here to enter text.](#)

Incident #: [Click here to enter text.](#)

Was an autopsy performed? Yes No

Was a toxicology test performed? Yes No

Date of Results: [Click here to enter a date.](#)

If prescription, please provide the following information:

Amount prescribed: [Click here to enter text.](#)

Amount found: [Click here to enter text.](#)

Name and Address of Prescriber:

[Click here to enter text.](#)

Name and Address of Pharmacy:

[Click here to enter text.](#)

Date Issued: [Click here to enter a date.](#)

Dosage: [Click here to enter text.](#)

Name of Narcotic Treatment Center: [Click here to enter text.](#)

**List All Substances/Chemicals/Drugs/Alcohol/Poisons
That Tested Positive and the Levels**

Substances/Chemicals/Drugs/Alcohol/Poisons	LEVELS
Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.

Decedent's Age: [Click here to enter text.](#)

Gender: [Click here to enter text.](#)

Race: [Click here to enter text.](#)

Marital Status: [Choose an item.](#)

County of Residence: [Click here to enter text.](#)

Describe drug(s) evidence found on person/scene (i.e., packing, stampings, markings, etc.)

[Click here to enter text.](#)

Additional notes/remarks:

[Click here to enter text.](#)

Submit completed form to:

By email to: ra-daod@pa.gov

or by fax to: 717-787-6285

For questions and additional information, contact:

Kathy Jo Stence, Drug and Alcohol Program Analyst

Department of Drug and Alcohol Programs

Bureau of Treatment, Prevention and Intervention

02 Kline Village

Harrisburg, PA 17104-1503

Email: kstence@pa.gov

Phone: 717-783-8200

APPENDIX C

MDAIR TREATMENT PROVIDER FORM



pennsylvania
DEPARTMENT OF DRUG AND
ALCOHOL PROGRAMS

METHADONE DEATH/INCIDENT CASE REVIEW FORM

Report type: Choose an item.

Date report filed: Click here to enter a date. **Report source:** _____

MDAIR ID#: _____ **Client ID# (if applicable):** _____

NAME: _____ **Client Gender :** _____

AGE: _____ **Date of treatment admission:** _____

Date of death or incident: Click here to enter a date.

Cause of death: _____

Manner of death: Natural Accident Suicide Homicide Undetermined

Was methadone a cause or contributing factor in the death: _____

DDAP obtained the following official report(s): Police Coroner Medical Examiner

Individual's general condition at the time of death or incident (e.g., physically or mentally ill, ability impaired, etc.):

Description of incident (Include any external factors that contributed to the death or incident):

Was anyone else harmed as a result of this death/incident: YES NO

- If yes, describe:

1. Source Providing methadone:

Medication assistance program Illicit Source Physician **Type of physician:** _____

2. Patient Length of time in client or being RX Methadone:

- < 2 weeks
 2 weeks- 1 month
 1-3 months
 3-6 months
 6-12 months
 1-2 years
 > 2 years

3. Methadone dosage at the time of incident or death: _____
4. Date of last methadone dosage change: _____ Previous dosage: _____
5. Take home medication: _____ How many per week: _____
6. Date of last *face-to-face* visit with methadone prescribing physician: _____

6a. Purpose of the visit: _____

7. Indicate the *date and length* of each counseling sessions for the 90 days prior to the incidents:

Group sessions: _____

Individual sessions: _____

Other counseling sessions (specify): _____

DATES:

8. Reported use of any other prescription and/or other drugs use? NO Yes (if yes, complete chart)

Name of drug (including prescriptions)	Dosage (if any)	Frequency

8a. Did the treatment plan address the drugs listed above: _____ Choose an item.

8b. Documentation of the NTP physician consulting with other prescribing providers: _____

9. ****Number of Urinalysis in the 90 days prior to the death or incident:** _____
***the above question must be answered for MAT cases, optional for other source*

9a. How many of the above Urinalysis were scheduled: _____ Unscheduled: _____

9b. How many were positive: _____

9c. Below provide dates and drug(s) for positive results:

Date	Drug

10. Clinic/physician response to positive urinalysis and/or use of other contraband drugs, including prescriptions:

- Was there an increase in individual counseling sessions? YES NO
- Was there an increase in group counseling sessions? YES NO
- OTHER:

10a. Was the individual adherent to treatment plan and/or recommendation(s): YES NO

If no, state how the individual failed to adhere to their treatment plan and/or recommendation(s):

11. Other medical diagnosis:

12. Was law enforcement involved: YES NO

- *If yes, what agency and contact person:* _____

13. Was a toxicology test performed: YES NO

If yes, a list of all substances/chemicals/drugs/alcohol/poisons that tested positive and levels below:

SUBSTANCES/CHEMICALS/DRUGS/ALCOHOL/POISONS	LEVELS

14. Were any criminal charges filed as a result of the incident or death: YES NO

APPENDIX D

MDAIR GENERAL REPORTING FORM



METHADONE DEATH/INCIDENT GENERAL REPORTING FORM

We understand you may not have all the requested information. Please provide whatever information you have available below.

Report type: Choose an item.

Date report filed: Click here to enter a date.

Name of individual filing report: _____

Contact phone #: _____

Relationship to individual involved in death or incident: Choose an item.

Information regarding the individual involved in incident or death

First name: _____ **Last name:** _____

Client Age: _____ **Client Gender :** Choose an item.

Race: _____ **Ethnicity:** Choose an item.

Marital Status: Choose an item.

Date of death or incident: Click here to enter a date.

Location of death or incident(city and state): _____

Manner of death: Natural Accident Suicide Homicide Undetermined

Description of incident (Please include how methadone was a contributing factor to the incident/death):

Was anyone else harmed as a result of this death/incident: YES NO

- If yes, describe:

15. Source Providing methadone:

Drug treatment program Illicit Source Unknown

Physician Type of physician (if Known) _____

16. Methadone dosage at the time of incident or death: _____

17. Any other prescription and/or other drugs use? NO Yes (if yes, complete chart)

Name of drug (including prescriptions)	Dosage (if any)	Frequency

18. Other medical conditions:

Is this matter being investigated? YES NO UNKNOWN

- If yes, by whom: _____

Medical Providers (including drug treatment):

Provider Name: _____

Address : _____

Telephone: _____

Provider Name: _____

Address : _____

Telephone: _____

APPENDIX E

MDAIR ACTION – DEATH FORM

MDAIR CASE # _____

Natural Cause Death – No Coroner exam performed

Manner cause of death: _____

Client First Name & Last initial: _____

Date of death: _____ **Date of report:** _____

DDAP visit conducted: YES NO **Date of visit:** [Click here to enter a date.](#)

Citation(s) given: YES NO

REQUESTED OR OBTAINED REPORTS/RECORDS:	DATE REQUESTED	CONTACT PERSON:	DATE RECEIVED
<input type="checkbox"/> Coroner			
<input type="checkbox"/> Police: (<input type="checkbox"/> City <input type="checkbox"/> County <input type="checkbox"/> State)			
<input type="checkbox"/> Police: (<input type="checkbox"/> City <input type="checkbox"/> County <input type="checkbox"/> State)			
<input type="checkbox"/> Treatment Provider			
<input type="checkbox"/> Medical Provider:			

Use below section if DDAP is still awaiting information:

Action/ contact (e.g., 2 nd call to abc for report)	Date

Appropriate for MDAIR Committee Review: Yes No

APPENDIX F

MDAIR ACTION - INCIDENT FORM

MDAIR CASE # _____

Nature of incident: _____

Client First Name & Last initial: _____

Date of Incident: [Click here to enter a date.](#) **Date of report:** [Click here to enter a date.](#)

DDAP visit conducted: YES NO **Date of visit:** [Click here to enter a date.](#)

Citation(s) given: YES NO

REQUESTED OR OBTAINED REPORTS/RECORDS:	DATE REQUESTED	CONTACT PERSON:	DATE RECEIVED
<input type="checkbox"/> Coroner			
<input type="checkbox"/> Police: (<input type="checkbox"/> City <input type="checkbox"/> County <input type="checkbox"/> State)			
<input type="checkbox"/> Police: (<input type="checkbox"/> City <input type="checkbox"/> County <input type="checkbox"/> State)			
<input type="checkbox"/> Treatment Provider			
<input type="checkbox"/> Medical Provider:			

Use below section if DDAP is still awaiting information:

Action/ contact (e.g., 2 nd call to abc for report)	Date

Appropriate for MDAIR Committee Review: Yes No