CONTROLLED SUBSTANCES AND ENFORCEMENT

Drug Diversion Reporting Requirements

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DEA Reporting Requirements for Drug Diversion

I. Introduction

The Drug Enforcement Administration (“DEA” or “Administration”) has promulgated regulations according to the Controlled Substances Act, 21 U.S.C. §§ 801, et. seq., in order to prevent and report instances of drug diversion. The regulations setting forth the reporting requirements are found at 21 C.F.R. § 1301.76 for practitioners and at § 1301.74 for non-practitioners.

II. Reporting Requirements

A. If a registrant discovers the theft or significant loss of any controlled substances, the registrant must

(1) notify the DEA Field Division Office in his area in writing within one business day of discovery of the loss or theft and

(2) complete the DEA Form 106 regarding the loss or theft and submit it to the Field Division Office in his area.

21 C.F.R. § 1301.76(b), § 1301.74(c).

B. “When determining whether a loss is significant, a registrant should consider among others, the following factors:

(1) the actual quantity of controlled substances lost in relation to the type of business;

(2) The specific controlled substances lost;

(3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;

(4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known;

(5) Whether the specific controlled substances are likely candidates for diversion;

(6) Local trends and other indicators of the diversion potential of the missing controlled substance.”
C. 21 C.F.R. § 1301.74(c) provides the same reporting requirements for non-practitioners, but also mandates that “[t]he supplier is responsible for reporting all in-transit losses of controlled substances by the common or contract carrier” within the same time frame. The regulation also states that “[t]hefts and significant losses must be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action taken against them.” Id.

D. The manufacturer or distributor must also report the theft or loss in ARCOS (Automation of Reports and Consolidated Orders System), which is the system through which manufacturers and distributors must report all of their controlled substances transactions. 70 Fed. Reg. 47094. The DEA also recommends that manufacturers/distributors notify local law enforcement of the theft or significant loss. Id.

III. Definitions

A. Registrant: “any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958). Every person who manufactures or distributes any controlled substance or list I chemical or dispenses any controlled substance must obtain a registration with the Attorney General. 21 U.S.C. § 822(a).1

B. Practitioner: “a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.” 21 U.S.C. § 802(21).

C. Non-practitioners include manufacturers, packagers, labelers, distributors, importers, exporters, narcotic treatment programs, and compounders for narcotic treatment programs.

http://www.deadiversion.usdoj.gov/pubs/manuals/sec/sec_non_prac.htm

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1 21 C.F.R. § 1301.02 states that “[a]ny term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.”
IV. DEA Advice

A. The DEA mandates that the initial notification be in writing and recommends that it be completed by fax, as U.S. mail may involve delays. 70 Fed. Reg. 47094. The DEA encourages registrants to make the report through their online application system. [http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html](http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html)

B. DEA advises that registrants should report even the suspected theft or significant loss of a controlled substance. 70 Fed. Reg. 47094. After initial notification, a registrant then has the opportunity to investigate the theft or significant loss before having to submit the DEA Form 106. *Id.* However, if after 60 days from the initial notification the investigation is still ongoing, DEA recommends that the registrant provide the DEA with an update on the matter. *Id.* DEA Form 106 should be submitted once the circumstances surrounding the theft or significant loss are clear. *Id.* If after investigating the matter the registrant determines that no theft or significant loss occurred, the registrant need not submit DEA Form 106. *Id.*

C. Registrants should note that “DEA Field Division Office” is a term of art that refers to the 20 DEA divisions in the United States. For example, the Chicago Division includes Indiana, Minnesota, North Dakota, Wisconsin and much of Illinois. Therefore, even though DEA has a District Office in Minneapolis, a Minnesota registrant that discovers theft or significant loss must notify the Field Division Office in Chicago within one business day. See Larry K. Houck, *The Drug Enforcement Administration’s Final Rule on Theft and Significant Loss Reporting: We Can See More Clearly Now*, 61 Food Drug L. J. 1, 8-9 (2006).

Minnesota Board of Pharmacy Rules

I. Controlled Substances Reporting Requirements

A. The Minnesota Board of Pharmacy Rules require any pharmacy, drug wholesaler, drug manufacturer, or controlled substance researcher who detects theft or significant loss of a controlled substance to immediately report the theft or loss in writing to the DEA.
Minnesota Vulnerable Adult Act

I. Introduction.

Minnesota’s Vulnerable Adult Act (“VA Act”) sets up a system whereby maltreatment of vulnerable adults is reported and, if appropriate, investigated and prosecuted. It requires mandatory reporting of suspected maltreatment by certain caregivers, and encourages others to voluntarily report suspected maltreatment. Reports are generally investigated and, where the report is substantiated, certain notification and records are made, as well as referral for criminal prosecution, if appropriate. Failure to follow the reporting requirements of the VA Act can result in criminal, civil, and licensing penalties for a provider of care.

II. Who Is a Vulnerable Adult?

A. The VA Act defines a “vulnerable adult” as a person 18 or older who falls into at least one of the following categories:

1. The person, regardless of residence or whether any type of service is received, possesses a physical or mental infirmity or other physical, mental, or emotional dysfunction that impairs the individual’s ability to provide adequately for the individual’s own care without assistance, including the provision of food, shelter, clothing, health care, or supervision, and because of the dysfunction or infirmity and the need for care or services, the individual has an impaired ability to protect the individual’s self from maltreatment.  

   2 Minn. Stat. § 626.5572, subd. 21.

2. The person is a resident or an inpatient of a facility, including a hospital or other facility licensed by the Department of Health, a nursing home, a residential or nonresidential facility licensed by the Department of Human Services, a licensed home care provider, or a personal care attendant service.

3. The person receives services at or from a facility required to be licensed to serve adults, except that a person receiving outpatient services for treatment of chemical dependency or mental illness, or one who is served in the Minnesota sex offender program on a court-hold order for commitment, or is committed as a sexual psychopathic personality or as a sexually dangerous person is not considered a vulnerable adult solely by reason of that status or care.

4. The person receives services from a licensed home care provider or from a person or organization that exclusively offers, provides or
arranges for personal care attendant services under the medical assistance program.

B. This means that any person who resides in a licensed residential facility is a vulnerable adult solely by reason of receiving those services.

III. What Is Maltreatment?

“Maltreatment” falls into three categories: abuse, neglect, and financial exploitation. Any one of these constitutes reportable maltreatment. Instances of drug diversion have the potential to fall into any of these three categories.

A. Abuse. “Abuse” in the context of drug diversion includes all of the following:

1. Criminal acts. An act against a vulnerable adult that constitutes a violation of, an attempted violation of, or aiding and abetting of the use of drugs to injure or facilitate a crime.

2. Other acts. Acts which produce or could reasonably be expected to produce physical pain or injury or emotional distress, including but not limited to the following:

   a) the use of any aversive or deprivation procedure, unreasonable confinement, or involuntary seclusion, including the forced separation of the vulnerable adult from other persons against the will of the vulnerable adult.

   The act of depriving a vulnerable adult of drugs intended for the vulnerable adult may qualify as the use of a deprivation procedure, thereby constituting abuse;

   and

   d) the use of any aversive or deprivation procedures for persons with developmental disabilities or related conditions not authorized by statute.

3. The act of forcing, compelling, coercing, or enticing a vulnerable adult against the vulnerable adult’s will to perform services for the advantage of another.³

   The act of forcing a vulnerable adult to participate in the act of drug diversion may qualify as abuse under this definition.

³ Minn. Stat. § 626.5572, subd. 2.
B. **Neglect.** Neglect means the following:

1. The failure or omission by a caregiver to supply a vulnerable adult with care or services, or the absence or likely absence of care or services, including but not limited to drugs or medication, which are reasonable and necessary to maintain the vulnerable adult’s physical or mental health or safety, considering the physical and mental capacity or dysfunction of the person.4

Nothing requires a caregiver, if regulated, to provide services in excess of those required by the caregiver’s licensure, certification, registration, or other regulations.

C. **Exceptions for Abuse and Neglect.** The following are exceptions to the above definitions of abuse and neglect that could apply in the context of drug diversion, except that none of these applies if there is criminal conduct involved.

1. **Accidents.** Sudden, unforeseen and unexpected occurrences which are not likely to occur and which could not have been prevented by the exercise of due care. If the vulnerable adult is receiving services from a facility, the facility and the person providing services must also be in compliance with the laws and rules relevant to the occurrence or event in order for the occurrence to be considered an accident.

D. **Additional Exception for Neglect.**

1. **Errors.** An error in the course of therapeutic conduct to a vulnerable adult that results in injury or harm is not neglect if:

   - the necessary care is provided in a timely fashion;
   - after receiving care, the attending physician determines that the vulnerable adult can be restored to his/her pre-existing condition;
   - the error is not a part of a pattern of errors by the individual; and
   - if the error occurs in a facility, the facility takes corrective action and implements measures to reduce the risk of further occurrence of similar errors.

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4 Minn. Stat. § 626.5572, subd. 17.
E. **Financial Exploitation.** Any of the following acts are financial exploitation if it results or is likely to result in detriment to the vulnerable adult:

1. **Breach of a fiduciary duty.** A person with a fiduciary duty to the vulnerable adult engages in an unauthorized expenditure of the vulnerable adult’s funds or fails to use the vulnerable adult’s financial resources to provide food, clothing, shelter, health care, therapeutic conduct or supervision.

   Such a breach may be found where a fiduciary diverts a vulnerable adult’s drugs purchased with the vulnerable adult’s funds, thereby failing to provide necessary care.

2. **Unauthorized use of funds.** Any person, without legal authority, willfully uses, withholds, or disposes of a vulnerable adult’s funds; obtains services for the person’s own benefit; acquires possession or control of, or an interest in, funds or property of a vulnerable adult through the use of undue influence, harassment, duress, deception, or fraud; or forces, compels, coerces, or entices a vulnerable adult against the vulnerable adult’s will to perform services for the profit or advantage of another. This includes theft.

   Such unauthorized use of funds may be found where a person diverts drugs purchased with the vulnerable adult’s funds or where a person forces a vulnerable adult to participate in drug diversion for the profit or advantage of another.

   Nothing in these definitions requires a facility to perform financial management or supervise financial management except as otherwise required by law.\(^5\)

IV. **What Should Happen if Maltreatment Occurs or Is Suspected?**

The VA Act requires certain people to report suspected maltreatment to the appropriate authorities. In addition, anyone may voluntarily report suspected maltreatment. Any reporter has certain rights and protections under the VA Act. These are intended to encourage and facilitate reporting.

A. **Mandated Reporters.** Any professional or professional’s delegate who cares for vulnerable adults, who provides social services, who works in any health care facility, who works in a rehabilitation facility certified by the commissioner of jobs and training, who works in law enforcement or education, as well as medical examiners and coroners, are mandated reporters.

\(^5\) Minn. Stat. § 626.5572, subd. 9.
This means that any employee or person providing services in a mental health residential facility or another similar program is a mandated reporter.

B. Voluntary Reporting. Anyone may voluntarily report known or suspected maltreatment of a vulnerable adult.

C. Triggers of Mandatory Reporting. A mandated reporter must report known or suspected maltreatment in the following circumstances:

1. The mandated reporter has reason to believe that a vulnerable adult is being or has been maltreated.

2. The mandated reporter has knowledge that a vulnerable adult has sustained a physical injury which is not reasonably explained.

3. Suspected maltreatment prior to admission. If the adult is a vulnerable adult solely by reason of being admitted to a facility, a mandated reporter is not required to report suspected maltreatment prior to admission unless the individual was admitted from another facility and the reporter has reason to believe the maltreatment may have occurred at the other facility, or the reporter knows or has reason to know that the person is vulnerable because of a physical or mental infirmity in addition to being admitted to a facility.

4. Errors. Mandated reporters must report any error in the course of therapeutic conduct that results in injury or harm, which reasonably requires the care of a physician. If the reporter or facility believes that an investigation will determine that the reported error was not neglect because the error falls into the error exception in the definition of neglect, the reporter or facility can provide this information to the common entry point or directly to the Department of Human Services.

D. Reports Must Be Made Immediately. “Immediately” means as soon as possible but no longer than 24 hours from the time knowledge that the incident has occurred has been received.

E. To Whom Reports Must Be Made. Reports must be made to the common entry point, which is the entity designated in each county to receive VA reports. A report may be made by the mandated reporter directly to the common entry point, or, if the facility has an internal reporting procedure, the mandated reporter may meet the reporting requirement under the VA Act by reporting internally. The facility is then responsible for immediately reporting the maltreatment to the common entry point.
1. **Internal reporting.**

   a) If a facility has an internal reporting procedure, a mandated reporter may meet the VA Act requirements by reporting internally.

   b) Once the facility receives a report from a mandated reporter, the facility is responsible for reporting to the common entry point immediately.

   c) The facility must give the mandated reporter a written report stating whether a report to the common entry point was made. This written notice must be given to the mandated reporter within two working days and in a manner that protects the confidentiality of the reporter. This notice must also state that if the mandated reporter is not satisfied with the action taken by the facility, the mandated reporter may report externally. The notice must also state that the facility is prohibited from retaliating against a mandated reporter who makes an external report in good faith.

   d) Nothing may prohibit a mandated reporter from reporting externally.

2. **External reporting.**

   a) A mandated reporter may always make a report directly to the common entry point.

   b) A mandated reporter who is not in a facility with an internal reporting procedure must report directly to the common entry point.

   c) A facility may not retaliate against a mandated reporter who reports an incident to the common entry point in good faith.

**F. Report Contents.**

1. Reports may be made orally to the common entry point.

2. To the extent possible, the report should contain sufficient content to identify the vulnerable adult, the caregiver, the nature and extent of the suspected maltreatment, any evidence of previous maltreatment, the name and address of the reporter, the time, date and location of the incident, and any other information that the
reporter believes might be helpful in investigating the suspected maltreatment.

3. A mandated reporter may disclose data that is not public and medical records to the extent necessary to comply with the reporting requirement.  

4. If a reporter wants to receive notice of the initial and final disposition of the report, the reporter should make that request at the time the report is made.

5. A boarding care home that is licensed under sections 144.50 to 144.58 and certified under Title 19 of the Social Security Act, a nursing home that is licensed under section 144A.02 and certified under Title 18 or Title 19 of the Social Security Act, or a hospital that is licensed under sections 144.50 to 144.58 and has swing beds certified under Code of Federal Regulations, title 42, section 482.66, may submit a report electronically to the common entry point instead of submitting an oral report. The report may be a duplicate of the initial report the facility submits electronically to the commissioner of health to comply with the reporting requirements under Code of Federal Regulations, title 42, section 483.13.

G. **Protections for Reporters.** The VA Act includes several protections for reporters.

1. **Immunity.** Any person who makes a good faith report, or who knows or who has reason to know that a report to the common entry point has been made and who in good faith participates in an investigation of alleged maltreatment, is immune from any civil or criminal liability that might otherwise result from making the report or from participating in the investigation, or for failure to comply fully with the reporting obligation of the VA Act.

2. **Confidentiality.** The identity of any reporter may not be disclosed, except with the consent of the reporter or upon a written finding by a court that the report was false and there is evidence that the report was made in bad faith.

3. **Retaliation against reporters and vulnerable adult subjects of reports is prohibited.**
   a) Facilities and persons are prohibited from retaliating against anyone who makes a report in good faith, or against

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6 Minn. Stat. § 626.557, subd. 4.
a vulnerable adult with respect to whom a report is made, because of the report.

b) Penalties for retaliation include civil liability under the Whistleblower statute, Minn. Stat. § 181.931 to 181.935, as well as actual damages, punitive damages up to $10,000 and attorney’s fees.

c) There is a presumption that if any adverse action toward a reporter or vulnerable adult involved in a report occurs within 90 days of the report, that the adverse action is retaliatory. Adverse actions include discharge or transfer from the facility, discharge or termination of employment, demotion or reduction in remuneration for services, restriction or prohibition of access to the facility or its residents, or any restriction of rights from the patient bill of rights.

H. Other Reports.

1. Emergency or medical care. VA reporting should not interfere with emergency or medical care for the person injured.

2. Law enforcement. Nothing in the VA Act precludes a person from reporting an incident to law enforcement, but a report to the common entry point is also required. The common entry point must notify law enforcement if it is determined that criminal activity is suspected.

V. What Happens Once a Report Is Made?

The following information describes what will happen after a person or facility reports maltreatment to a common entry point.

A. Screening. When a common entry point receives a report, it must screen the report for immediate risk and make necessary referrals:

1. If the common entry point determines that there is an immediate need for adult protective services, the common entry point must notify the appropriate county agency.

2. If the report contains suspected criminal activity, the common entry point must notify the appropriate law enforcement agency.

3. The common entry point must refer all reports of alleged or suspected maltreatment to the appropriate lead investigative

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7 Minn. Stat. § 626.557, subd. 17.
agency as soon as possible, but no longer than two working days. For programs serving people with mental illnesses, the appropriate lead investigative agency will generally be the Department of Human Services. The Department of Health is the lead investigative agency for the facilities which are licensed or are required to be licensed as hospitals, home care providers, nursing homes, residential care homes, boarding care homes, or residential facilities are also federally certified as intermediate care facilities that serve people with developmental disabilities. The Department of Human Services is the lead agency for the programs licenses or required to be licensed as adult day care, adult foster care, programs for people with developmental disabilities, mental health programs, or chemical health programs. The county social service agency or its designee is the lead investigative agency for all other reports.8

4. If the report contains information about a suspicious death, the common entry point must immediately notify the appropriate law enforcement agencies and the appropriate ombudsman.

B. Response to Reports.

1. Law enforcement is the primary agency to conduct investigations of any incident in which there is reason to believe that a crime has been committed. Under the VA Act, law enforcement is supposed to initiate a response immediately.

2. If adult protective services are also involved, law enforcement is supposed to coordinate with adult protective services. Again, adult protective services are supposed to initiate a response immediately. The duties of the county social services agency include the following:

a) Immediate assessment, and emergency and continuing protective services for purposes of preventing further maltreatment and for safeguarding the welfare of the maltreated vulnerable adult;

b) In cases of suspected sexual abuse, appropriate medical examination and treatment;

c) When necessary to protect the vulnerable adult from further harm, removal from the situation in which the maltreatment occurred;

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8 Minn. Stat. § 626.5572 subd. 13.
d) If it appears that conditions exist which place other vulnerable adults at risk of maltreatment, further investigative services and protective services as needed; and

e) When necessary to protect a vulnerable adult from serious harm, intervention by seeking a restraining order, appointment of a guardian, replacement of a guardian, or referral to the county attorney for possible criminal prosecution of the perpetrator.

3. The lead investigative agency, which is the Department of Human Services for most programs serving the mentally ill, must also complete the investigative process for reports within its jurisdiction, regardless of the involvement of law enforcement or adult protective services. This makes sense, because the other agencies have different priorities: the primary duty of law enforcement is to investigate and prosecute crimes and the primary duty of adult protective services is to provide immediate protection from harm. It is the lead investigative agency which investigates the VA aspect of an incident, makes reports to licensing boards and maintains records of perpetrators of substantiated maltreatment.

4. The lead investigative agency must also develop guidelines for prioritizing reports for investigation.9

C. Investigations.

1. The appropriate agency (lead investigative agency, law enforcement, adult protective services) will investigate the report and must coordinate with the other agencies involved. The agency may also determine that no investigation is warranted.

2. The lead investigative agency has the right to enter facilities, inspect, and copy records as part of the investigation. It has access to not public data and to medical records that are maintained by facilities, to the extent necessary to conduct its investigation.10

3. Upon request of the reporter, the lead investigative agency must notify the reporter that it has received the report, and provide the reporter information on the initial disposition of the report within five days of receiving the report, provided that notification will not endanger the vulnerable adult or hamper the investigation.

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9 Minn. Stat. § 626.557, subd. 9b.
10 Minn. Stat. § 626.557, subd. 9b.
4. The lead investigative agency has 60 days to complete its investigation and make a final disposition. The agency may take more than 60 days, but must notify the vulnerable adult, or the adult’s legal guardian, and the facility, if applicable.\(^\text{11}\)

According to the Department of Human Services, 27% of investigations are completed within 60 days, 41% are completed within 90 days and 53% are completed within four months.

5. A facility may also conduct its own investigation, but it should focus more on whether internal policies and procedures were violated. Even if a facility conducts an investigation, the lead investigative agency will also conduct its own investigation.

D. Final Dispositions.

1. Upon the conclusion of every investigation the lead investigative agency must make a final disposition. A final disposition is the determination that a report of maltreatment is substantiated, inconclusive, false, or that no determination will be made. If the final disposition is of substantiated maltreatment, the final disposition must also identify, if known, which individual or individuals were responsible for the substantiated maltreatment, and whether a facility was responsible for the substantiated maltreatment.\(^\text{12}\)

2. In determining whether the facility or individual is responsible for maltreatment, the following factors must be considered:

   a) Whether the actions of the facility or individual were in accordance with an erroneous physician order, prescription, resident care plan, or directive. This is not a mitigating factor, however, if the facility or individual is responsible for the errors or knows or should have known of the errors and took no reasonable measures to correct the defect before administering care.

   b) The comparative responsibility between the facility, other caregivers and requirements placed upon the employee, including the facility’s compliance with related regulatory standards and factors such as the adequacy of facility policies and procedures, training, supervision, staffing levels and the scope of the individual employee’s authority.

\(^{11}\) Minn. Stat. § 626.557, subd. 9c.
\(^{12}\) Minn. Stat. § 626.5572, subd. 8.
c) Whether the individual or facility followed professional standards in exercising professional judgment.\textsuperscript{13}

3. When substantiated maltreatment is determined to have been committed by an individual who is also the facility license holder, both the individual and the facility must be determined responsible for the maltreatment.\textsuperscript{14}

4. Within ten calendar days of completing the final disposition, the lead investigative agency must provide a copy of the public investigation memorandum to the following persons:

a) the vulnerable adult or the vulnerable adult’s guardian or health care agent, provided the notice would not endanger the well-being of the vulnerable adult;

b) the reporter, if the reporter requested the notification when making the report and provided the notice would not endanger the well-being of the vulnerable adult;

c) the alleged perpetrator, if known;

d) the facility; and

e) the appropriate ombudsman.

The agency must also notify the vulnerable adult who is the subject of the report, the alleged or substantiated perpetrator, and the facility, of their appeal rights under the VA Act.

4. The public investigation memorandum must contain the following information, which is public:

a) the name of the facility investigated;

b) a statement of the nature of the alleged maltreatment;

c) pertinent information obtained from medical or other records reviewed;

d) the identity of the investigator;

e) a summary of the investigation’s findings;

\textsuperscript{13} Minn. Stat. § 626.557, subd. 9c.

\textsuperscript{14} Minn. Stat. § 626.557, subd. 9c.
f) a statement of whether the report was found to be substantiated, inconclusive, false or that no determination will be made;

g) a statement of any action taken by the facility;

h) a statement of any action taken by the lead investigative agency; and

i) when a lead investigative agency’s determination is of substantiated maltreatment, a statement of whether an individual, individuals, or a facility were responsible for the substantiated maltreatment, if known.

The investigation memorandum must be written in a manner which protects the identity of the reporter and of the vulnerable adult, and may not contain the names of, or to the extent possible, private information about, the vulnerable adult, the alleged perpetrator, and individuals interviewed as part of the investigation.\(^\text{15}\)

5. The lead investigative agency must regularly provide investigation memoranda for substantiated reports to the appropriate licensing boards, and must include the names of substantiated perpetrators.

6. The commissioner of human services must also be notified of substantiated reports and must maintain records of substantiated perpetrators.

E. Appeals.

1. Who may appeal.

a) Any individual or facility that a lead investigative agency determines has maltreated a vulnerable adult, or

b) A vulnerable adult who is the subject of a report, or the vulnerable adult’s designee, regardless of the lead investigative agency’s determination.

2. Appeal options.

a) Request for reconsideration. A request that the lead investigative agency reconsider its final disposition must be made in writing and submitted to the lead investigative agency within 15 calendar days after receipt of notice of the final disposition.

\(^{15}\) Minn. Stat. § 626.557, subd. 12b.
b) If the lead investigative agency denies the request or fails to act within 15 days after receiving the request, the person or facility may submit a written request for a fair hearing under the Administrative and Judicial Review of Human Services Matter statute, Minn. Stat. § 256.045.

c) If, as a result of a reconsideration, review, or hearing, the lead investigative agency changes the final disposition, or if the final disposition is changed on appeal, the lead investigative agency shall notify the parties specified in paragraph D.3. above.

VI. What Is at Stake if Someone Does Not Do What They Are Supposed To?

A. Civil Liability.

1. A mandated reporter who negligently or intentionally fails to report is liable for damages caused by the failure.\textsuperscript{16}

2. A person or facility who intentionally makes a false report is liable for any actual damages suffered by the reported facility, person or persons, and for punitive damages up to $10,000 and attorney’s fees.\textsuperscript{17}

3. A vulnerable adult who is the victim of financial exploitation has a cause of action against a person who committed the financial exploitation and is entitled to recover damages equal to three times the amount of compensatory damages or $10,000, whichever is greater. In addition, the vulnerable adult is entitled to recover attorney fees and costs, including reasonable fees for the services of a guardian or conservator or guardian ad litem incurred in connection with a claim for financial exploitation. A cause of action for financial exploitation may be brought regardless of whether there has been a report or final disposition or a criminal complaint or conviction related to the financial exploitation.

B. Criminal Liability.

1. A mandated reporter who is required to report under the VA Act, who knows or has reason to believe that a vulnerable adult is being or has been maltreated and who intentionally fails to make a report, knowingly provides information which is false, deceptive or misleading or who intentionally fails to provide all of the material circumstances surrounding the incident which are known to the reporter when the report is made, is guilty of a misdemeanor.

\textsuperscript{16} Minn. Stat. § 626.557, subd. 7.

\textsuperscript{17} Minn. Stat. § 626.557, subd. 6.
2. It is a gross misdemeanor to intentionally fail to make a report if the mandated reporter knows the maltreatment caused or contributed to the death or great bodily harm of the vulnerable adult and the failure to report causes or contributes to the death or great bodily harm or protects the interests of the mandated reporter.\(^{18}\)

Reporting to Law Enforcement of Crimes Occurring in Federally Funded Long-Term Care Facilities

I. Introduction

In 2010 the Social Security Act ("SSA" or "the Act"), 42 U.S.C. § 1301 \textit{et seq}, was amended by Sections 6701-6703 of the Patient Protection and Affordable Care Act of 2010, H.R. 3590 ("PPACA"). The amendment created Section 1150B\(^{19}\) of the SSA, which states that certain individuals connected with a federally funded long-term care ("LTC") facility must report any reasonable suspicion of a crime against a facility resident. Consequently, any suspicion of drug diversion that qualifies as a crime against a LTC resident would implicate the reporting requirements under the Act.

II. Determination and Notification

A. Under the Act, the owner or operator of a long-term care facility that receives Federal funds under the SSA must annually determine whether the facility received at least $10,000 in SSA funds during the preceding year.\(^{20}\)

B. If the owner or operator determines that the facility received at least $10,000 in SSA funds the previous year, the owner or operator must annually notify each covered individual of that individual’s obligation to comply with the reporting requirements.\(^{21}\)

C. The term ‘covered individual’ means each individual who is an owner, operator, employee, manager, agent, or contractor of a long-term care facility that is the subject of a determination described above.\(^{22}\)

\(^{18}\) Minn. Stat. § 609.234.
\(^{19}\) To be codified as 42 U.S.C. § 1320b-25.
\(^{20}\) SSA § 1150B(a)(1).
\(^{21}\) SSA § 1150B(a)(2).
\(^{22}\) SSA § 1150B(a)(3).
III. Reporting Requirements

A. Each covered individual must report to the Secretary and one or more law enforcement entities for the political subdivision in which the facility is located any reasonable suspicion of a crime (as defined by the law of the applicable political subdivision) against any individual who is a resident of, or is receiving care from, the facility. ²³

B. The timing in which the individual must report the suspected crime varies depending upon the type of crime. If the events that cause the suspicion –

(1) result in serious bodily injury, the individual must report the suspicion immediately, but not later than two hours after forming the suspicion; and

(2) do no result in serious bodily injury, the individual shall report the suspicion not later than 24 hours after forming the suspicion. ²⁴

IV. Penalties

A. If a covered individual fails to abide by the above reporting requirements, the covered individual shall be subject to a civil money penalty up to $200,000 or up to $300,000 if the violation exacerbates the harm to the victim of the crime or results in harm to another individual. The individual may also be subject to exclusion from participation in any Federal health care program. While an individual is classified as an excluded individual, a LTC facility that employs that individual will be ineligible to receive SSA funds. ²⁵

B. If a LTC facility retaliates against an employee who reports a crime against a facility resident under the Act, the facility will be subject to a civil penalty up to $200,000 or classified as an excluded entity for two years, or both. ²⁶

²³ SSA § 1150B(b)(1).
²⁴ SSA § 1150B(b)(2).
²⁵ SSA § 1150B(c).
²⁶ SSA § 1150B(d).