Drug Diversion Investigative Agencies

This document is intended as an introduction to the various state and federal agencies that investigate cases related to diversion of controlled substances by healthcare professionals. If you suspect that diversion, tampering, or misuse of controlled substances within a healthcare facility or by a healthcare provider may be occurring, even if you have not yet begun or completed an investigation, consider calling the appropriate agency or agencies listed below.

Food and Drug Administration/Office of Criminal Investigations

<u>Description:</u> As the criminal investigative arm of the Food and Drug Administration (FDA), the mission of the Office of Criminal Investigations (OCI) is to conduct and coordinate investigations of suspected criminal violations of the Federal Food, Drug, and Cosmetic Act (FDCA) and other related Acts; the Federal Anti-Tampering Act (FATA); and other statutes including applicable Title 18 violations of the United States Code (USC); and to collect evidence to support successful prosecutions through the federal or state court systems as appropriate. OCI investigations concentrate on significant violations of these laws, with a priority on conduct that may present a danger to the public health.

When to contact: OCI's general areas of enforcement include, but are not limited to, product tampering, product substitution crimes, illegal diversion of pharmaceuticals and other related products, crimes involving the adulteration and misbranding of drugs, and Prescription Drug Marketing Act violations (drug samples). If you suspect, or have evidence that any of the above crimes have been committed or are currently occurring, contact OCI as soon as possible. It is not necessary for an investigation to be complete before contacting OCI.

<u>Information sharing:</u> All data related to ongoing/active investigations is confidential/protected nonpublic. Data may become public when an investigation has become fully adjudicated. Data may be provided to the public in the interest of public health or to other investigative organizations on a case-by-case basis, depending on the situation.

Contact information:

Ken Kulick (local) 651-433-5404 (office) 612-720-7677 (cell)

kenneth.kulick@oci.fda.gov

Chicago Field Office 1-800-521-5782 or 630-769-5520

(IL, IN, MI, MN, ND, SD, WI) (emergency contact)

Drug Enforcement Administration (DEA) Office of Diversion Control

<u>Description:</u> The mission of DEA's Office of Diversion Control is to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs.

When to contact: DEA registrants are required to notify the Drug Enforcement Administration, Minneapolis-St. Paul District Office, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete, and submit to the Minneapolis-St. Paul District Office, DEA Form 106 regarding the loss or theft. 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.

<u>All thefts must be reported</u> whereas losses should be assessed according to the criteria noted above.

Contact information:

Drug Enforcement Administration Minneapolis-St. Paul District Office Diversion Group 330 2nd Avenue South, Suite 450 Minneapolis, Minnesota 55401 (612) 344-4143 (General Diversion Line)

State/County Law Enforcement

<u>Description:</u> The mission of local law enforcement as it relates to drug diversion is to gather and evaluate evidence; take statements from victims, suspects and others; present cases to the County Attorney's office for prosecution, make arrests in cases of ongoing criminal activity or public safety, enlist the assistance of federal law enforcement when necessary; give expert testimony in those and other cases and liaison with health care facilities to assist them in the prevention of future crimes.

Local law enforcement represents a comprehensive and broad-based investigative resource. Local law enforcement has authority to investigate all crimes related to drug diversion, including but not limited to:

- Controlled substance crimes
- Homicide/manslaughter

- Assault
- Abuse
- Neglect
- Financial exploitation
- Theft
- Burglary
- Insurance fraud
- Identity theft

When to contact: Under the Minnesota statutes 152.025 and 609.52 the diversion of even one pill/dose of any controlled substance by "fraud, deceit, misrepresentation, or subterfuge" from its intended path from manufacturer to patient (or out of the waste stream) is a felony crime. If this controlled substance was diverted by any person in the period of time from dispensing (by pharmacy or physician) to consumption (or administration) by a patient, this act potentially constitutes the financial exploitation of a vulnerable adult. (609.2335); this is a mandatory reporting felony.

Health care facilities should voluntarily contact local law enforcement in all cases of diversion where an incident is suspected and where a suspect has been identified. It is important that law enforcement is brought in early to ensure that evidence is not lost or destroyed and that the elements of the crime(s) are appropriately investigated. Local law enforcement should be notified prior to questioning or approaching the suspect and the suspect should not be alerted to a potential criminal investigation. Law enforcement should be given opportunity to conduct the initial interviews with a suspect(s) regarding a diversion incident.

Due to the many jurisdictions involved, it is important that health care facilities obtain "buy in" by local law enforcement. It is suggested that all health care facilities reach out to their local law enforcement prior to a diversion incident. Contact numbers should be obtained and expectations discussed. It is recommended that the health care community approach local law enforcement under the principals of community oriented policing and request assistance with this community issue.

Contact information:

911 or local non-emergency number

Minnesota Department of Health

<u>Description:</u> The Minnesota Department of Health's Office of Health Facility Complaints (OHFC) has mandated responsibilities under both state and federal law and has statewide jurisdiction. OHFC investigates complaints related to health care providers licensed in the state of Minnesota (hospitals, nursing homes, home care providers, ambulatory surgery centers, home health agencies, ICF/MRs). The responsibility of OFHC as it relates to drug diversion is to triage and investigate complaints or facility reports involving allegations of drug diversion. During triage OHFC also verifies if law enforcement is aware of the allegation. If the complaint is related to a federally certified hospital, the complaint is sent to CMS for authorization of an investigation. Depending on the allegation, OHFC can refer the complaint or facility report to other lead

agencies, the police department or the various boards, including Board of Medical Practice, the Board of Nursing, and Board of Pharmacy for investigation. An investigator makes an on-site, unannounced, visit to the facility to investigate the allegation, which includes interviews of staff and patients, review of documentation and evaluation of the provider's compliance with the specific MN rules and statues and the Federal regulations. Violations of state and federal regulation are cited and a separate determination of maltreatment is made under Minnesota Statute, Section 626.557 and 626.5572 (VAA).

<u>Information Sharing:</u> Investigative information is shared according to the VAA. Public reports are shared with Licensing boards, the local police department and the city and county attorneys. For substantiated cases, non-public data is also shared with licensing boards, police departments and city and county attorneys.

<u>When to contact:</u> Under the VAA, mandated reporters are required to immediately report possible maltreatment to the common entry point. Federally certified nursing homes are also required to report to OHFC directly.

Contact information:

Email: health.ohfc-complaints@state.mn.us Phone: 651-201-4201 or 1-800-369-7994

Stella French, Director OHFC

Kris Lohrke, Assistant Director

651-201-4212 or stella.french@state.mn.us
651-201-4215 or kris.lohrke@state.mn.us

Minnesota Board of Pharmacy

<u>Description:</u> The Minnesota Board of Pharmacy exists to protect the public from adulterated, misbranded, and illicit drugs, and from incompetent, unethical, illegal or unprofessional conduct on the part of pharmacists or other licensees and registrants. The Board fulfills its mission through a combination of licensing activities, facility inspections, rule-making, provision of technical assistance, operation of the Minnesota Prescription Monitoring Program, complaint investigations and, when necessary, disciplinary activity.

The Board of Pharmacy investigates all complaints relating to alleged diversion of controlled substances within any facility that is licensed by the Board (pharmacies, drug manufacturers, drug wholesalers and controlled substance research facilities). The Board also investigates any alleged diversion of controlled substances by the individuals licensed or registered by the Board, regardless of the setting in which the diversion occurred. The Board receives DEA Form 106 loss forms on a regular basis and refers any cases involving the licensees or registrants of other licensing agencies to those agencies.

When to contact: Whenever diversion is alleged to have occurred within a pharmacy, drug manufacturing facility, drug wholesaling facility or controlled substance research facility. Also, whenever an individual licensed or registered by the Board (or who is employed by a facility licensed or registered by the Board) is alleged to have been involved in diversion (pharmacists, pharmacy technicians, pharmacy interns, controlled substance researchers and employees of drug manufacturers and wholesalers), regardless of where the diversion occurs.

In addition, if diversion happens within a hospital or long-term care facility and there is a reason to believe that action by a pharmacist or pharmacy could have contributed to the diversion, the Board should be contacted. (e.g. a delivery person from a pharmacy gives a controlled substance prescription to a patient of a long-term care facility, rather than to staff, and the patient takes a controlled substance prescribed for someone else).

Contact information:

Cody Wiberg, Pharm.D., M.S., R.Ph. Executive Director
Minnesota Board of Pharmacy
2829 University Avenue SE #530
Minneapolis, MN 55414
(651)201-2825
(651)201-2837 (fax)
Pharmacy.board@state.mn.us
Cody.wiberg@state.mn.us

Minnesota Board of Medical Practice

<u>Description:</u> The Board of Medical Practice is a state agency that licenses and regulates physicians, physician assistants, naturopaths, respiratory therapists, acupuncturists, athletic trainers and traditional midwives. The mission of the Board of Medical Practice is to protect the public's health and safety by assuring that the people who practice medicine or as an allied health professional are competent, ethical practitioners with the necessary knowledge and skills appropriate to their title and role. The Board carries out the majority of its mission through the work of its Licensure, Complaint Review, and Policy and Planning Committees.

The Board issues credentials, investigates complaints, imposes and monitors disciplinary actions and disseminates public information pertaining to its licensing, regulatory, and educational activities. The Board also interacts and shares non-public complaint and investigative data with other state licensing boards, state agencies, and enforcement authorities, when deemed necessary to protect the public, pursuant to state and federal statutes.

When to contact: Anyone seeking information about the status of an individual regulated by the Board of Medical Practice may contact the Board to obtain public licensing or disciplinary information. Any person who has knowledge of any conduct constituting grounds for discipline under the Board's regulatory statutes may file a complaint with the Board. Institutions, medical societies, insurers, licensed professionals, and the courts, have mandatory reporting obligations to the Board, as outlined in Minn. Stat. § 147.111.

Contact information:

General information:

Telephone: (612) 617-2130 Facsmile: (612) 617-2166

E-Mail: medical.board@state.mn.us
Website: http://www.bmp.state.mn.us

Licensing information:

Jeanne Hoffman, Licensure Coordinator

Telephone: (612) 548-2146

E-Mail: Jeanne.Hoffman@state.mn.us

Complaint and disciplinary information:

Ruth Martinez, Complaint Review Unit Supervisor

Telephone: (612) 548-2150

E-Mail: Ruth.Martinez@state.mn.us

Minnesota Board of Nursing

<u>Description:</u> The Board of Nursing is a regulatory agency of the State of Minnesota whose mission is to protect the public's health and safety by providing reasonable assurance that the persons who practice nursing are competent, ethical practitioners with the necessary knowledge and skills appropriate to their title and role. The Board strives to achieve its mission by:

- Carrying out activities authorized by Minnesota statutes and rules (licensing, discipline and nursing program approval)
- Maintaining current knowledge relevant to the education and practice of nurses.
- Disseminating information to nursing and the public.
- Operating an agency which utilizes human and fiscal resources efficiently and effectively.

The Board has developed an efficient, robust program to receive, investigate and resolve complaints alleging violations of the Minnesota Nurse Practice Act by nurses and applicants for licensure.

When to contact: Anyone with knowledge of any conduct constituting grounds for discipline by the Board may report the alleged violation to the Board. Additionally, nurse administrators and licensed health professionals may be obligated to report alleged violations to the Board (See Minn. Stat. sec. 148.263, subd. 2 and 3). Under certain circumstances, court administrators are obligated to report to the Board. (See Minn. Stat. sec. 148.263, subd. 5). The Board strongly encourages prompt reporting of suspected or verified diversion of controlled substances by a nurse, alteration of prescriptions or self-prescribing, nurse impairment while practicing or substandard practice by a nurse, particularly in medication administration and documentation.

Contact information:

Minnesota Board of Nursing Rene Cronquist, Director of Practice and Policy (612) 617-2198 Barbara Damchik-Dykes, Discipline Case Coordinator (612) 617-2199

(612) 617-2270 1-(888) 234-2690 www.nursingboard.state.mn.us nursingboard@state.mn.us