

# Cynthia Marcotte Stamer, P.C. SOLUTIONS LAWYER™

**Cynthia Marcotte Stamer**  
Board Certified – Labor and Employment Law  
Texas Board of Legal Specialization  
Direct Telephone: (972) 588.1860  
Mobile Telephone: (469) 767.8827  
Facsimile: (469) 814-8382  
E-Mail: [cstamer@solutionslawyer.net](mailto:cstamer@solutionslawyer.net)

**Helping Management Manage**

**Primary Office**  
6633 Dallas Parkway, Suite 600  
Addison, Texas 75001  
**Plano Office**  
3948 Legacy Drive  
Suite 106, Box 397  
Plano, Texas 75023

## **DEA Cautions Practitioners Must Restrict Delegation of Controlled Substance Prescribing Functions, Urges Adoption of Written Policies & Agreements**

*October 17, 2010*

Physicians, dentists, veterinarians, hospitals, and other persons prescribing or managing practitioners that prescribe controlled substances should obtain written agreements with staff and others communicating controlled substance prescriptions on their behalf and implement other suitable controls to ensure compliance with Drug Enforcement Administration requirements for prescribing controlled substances according to a new [DEA Statement of Policy On Role of Authorized Agents in Communicating Controlled Substance Prescriptions To Pharmacies](#) (Statement) published by the Department of Justice Drug Enforcement Administration (DEA) on October 6, 2010.

The Statement reflects that the DEA is concerned that about practitioners improperly delegating medical need determinations and other responsibilities for prescribing controlled substances. The Statement indicates that practitioners using agents to communicate controlled substance prescriptions should ensure that their delegations are appropriately documented by written agreements with the agents detailing the scope of their authority and implement background checks, monitoring, written and operational policies and procedures governing delegations and other controlled substance prescribing and other controls to appropriately comply with DEA controlled substance prescription mandates.

### **Controlled Substance Prescribing Restricted to DEA Authorized Practitioners**

Practitioners violating DEA requirements for prescribing controlled substances risk loss of DEA registration, licensure, peer review, employment discipline and other potential professional, administrative, civil and even criminal sanctions. Even the accusation of an alleged violation can create significant financial and professional consequences. Accordingly, each practitioner promptly should review the adequacy and defensibility of any delegation, recordkeeping and other controlled substance prescribing practices to minimize legal and professional exposures.

Under the Comprehensive Drug Abuse Prevention and Control Act of 1970 (CSA) and the Controlled Substances Import and Export Act (CSIEA) (21 U.S.C. 801-971), a valid prescription issued by a DEA-registered practitioner is required for dispensing a controlled substance. The DEA strictly regulates controlled substances because of their potential for abuse and likelihood to cause dependence when abused and because of their serious and potentially unsafe nature if not used under proper circumstances. Only practitioners with suitable DEA registration may prescribe controlled substances.

Existing rules prohibit DEA-registered practitioners from delegating their authority to prescribe controlled substances. To be effective (i.e., valid), a DEA-registered practitioner must issue the required prescription for a controlled substance for a legitimate medical purpose as determined by the practitioner acting in the usual course of professional practice. The registered practitioner actually must make the required determination of legitimate medical purpose underlying a controlled substance prescription. He cannot delegate responsibility for determining the legitimacy of the medical purpose for a controlled substance prescription or other core responsibilities.

### **DEA Permission To Delegate Communication Functions Very Limited**

While DEA rules prohibit a registered practitioner from delegating his core responsibilities pertaining to prescribing controlled substances to anyone else, DEA rules allow an individual practitioner to authorize an agent to perform a limited role in communicating controlled substance prescriptions to a pharmacy in order to make the prescription process more efficient. The ability to delegate these communication responsibilities is very restricted and requires that the practitioners apply appropriate controls to prevent delegation of core prescribing responsibilities.

In the Statement, the DEA cautions that DEA requires that DEA registered practitioners must be prepared to demonstrate that the registered practitioner alone makes all required medical determinations to prescribe the communicated controlled substances when delegating responsibility to communicate controlled substance prescriptions to pharmacies on their behalf to nurse or other person acting as the practitioner's agent.

DEA Regulation §1306.05(f) states that “[a] prescription may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations.” Accordingly, an authorized agent may prepare a controlled substance prescription only based on the instructions of the prescribing practitioner as to the required elements of a valid prescription and then provide the prescription to the practitioner to review and sign. The authorized agent does not have the authority to make medical determinations or to sign the prescription. Rather, the practitioner must personally make the medical need for and sign the prescription, whether manually or electronically. The prescribing practitioner cannot delegate his prescribing or signature authority.

Assuming that the practitioner properly retains control over the prescription of controlled substances, DEA regulations implementing the CSA specifically permit a practitioner to use an authorized agent to perform certain ministerial acts in the communication of prescription information to a pharmacy. The common means to communicate a prescription to a pharmacy include hand delivery, facsimile, phone call, or an electronic transmission. The Statement indicates that that for purposes of performing these delegated functions, the proper role of an agent depends upon the schedule of the controlled substance prescribed, the circumstances of the ultimate user, and the method of communication.

If and only if the appropriate restrictions and safeguards are applied as required for the nature of the controlled substance and the circumstances and means of prescribing and the practitioner properly retains control of and exercises the required core prescribing functions, the Statement provides that:

- An authorized agent of an individual practitioner may prepare a written prescription for the signature of the practitioner, provided that the practitioner, in the usual course of professional practice, has determined that there is a legitimate medical purpose for the prescription and has specified to the agent the required elements of the prescription.
- Where a DEA-registered individual practitioner has made a valid oral prescription for a controlled substance in Schedules III-V by conveying all the required prescription information to the practitioner's authorized agent, that agent may telephone the pharmacy and convey that prescription information to the pharmacist.
- In those situations that an individual practitioner has issued a valid written prescription for a controlled substance, and the DEA regulations permit the prescription to be transmitted by facsimile to a pharmacy, the practitioner's agent may transmit the practitioner-signed prescription to the pharmacy by facsimile.

#### **Adopt Controls & Safeguards To Manage Compliance & Risks**

Practitioners delegating communication duties must keep in mind that the practitioner generally remains responsible for delegated activities. In the event of a DEA investigation or certain other challenges, practitioners must be prepared that their practices met DEA requirements. To defend against this possibility, practitioners should implement written delegation policies and other procedures to facilitate their ability to withstand DEA scrutiny and defend against a claim of improper conduct by the practitioner or his delegated agent. Adopting written delegation agreements and other policies as specified in the Statement should be a core element of these processes. Other steps that prescribing practitioners also should consider include:

- Strictly complying with DEA requirements when prescribing controlled substances;
- Abstaining from delegation of, or delegating communication of controlled substance prescriptions except in strict and clearly documented compliance with DEA rules;
- Adopting and following written policies and procedures governing the prescription and handling of controlled substances including the scope of allowable delegation of communication functions;
- Requiring staff or others authorized to perform delegated communication functions to enter into signed written delegation agreements;
- Monitoring of prescribing and other dealings with controlled substances for potential noncompliance;
- Careful documentation of all activities involved with the prescription and handling of controlled substances or their prescriptions;
- Carefully restricting the individuals that with or without authorization could participate in the prescription or handling of controlled substance;
- Requiring drug and alcohol testing of physicians and other staff with involvement in the prescription or handling of controlled substance or who otherwise might be in a position to access the materials used in this process;
- Conducting appropriate training of DEA-authorized practitioners and their support staff regarding the appropriate procedures for handling and prescribing controlled substances;

- Conducting periodic background checks of staff and others who might participate in the prescription of or otherwise be in a position to access controlled substances or the tools for their access or prescription pursuant to written authorizations designed to comply with applicable Federal Trade Commission and other relevant laws; and
- Investigating and promptly redressing any known or suspected violation of DEA mandated or other policies regarding the prescription or handling of controlled substances.

#### **For More Information Or Assistance**

If you need assistance reviewing or responding to the DEA prescribing guidance contained in the Statement or addressing other health care related risk management or compliance concerns, the author of this update, attorney Cynthia Marcotte Stamer, may be able to help. Vice President of the North Texas Health Care Compliance Professionals Association, Past Chair of the ABA Health Law Section Managed Care & Insurance Section and the former Board Compliance Chair of the National Kidney Foundation of North Texas, Ms. Stamer has more than 23 years experience advising health industry clients about these and other matters. Ms. Stamer has extensive experience advising and assisting health care providers and other health industry clients to establish and administer compliance and risk management policies and to respond to DEA and other health care industry investigation, enforcement and other compliance, public policy, regulatory, staffing, and other operations and risk management concerns. A popular lecturer and widely published author on health industry concerns, Ms. Stamer continuously advises health industry clients about compliance and internal controls, workforce and medical staff performance, quality, governance, reimbursement, and other risk management and operational matters. Ms. Stamer also publishes and speaks extensively on health and managed care industry regulatory, staffing and human resources, compensation and benefits, technology, public policy, reimbursement and other operations and risk management concerns. Her insights on these and other related matters appear in the Health Care Compliance Association, Atlantic Information Service, Bureau of National Affairs, World At Work, The Wall Street Journal, Business Insurance, the Dallas Morning News, Modern Health Care, Managed Healthcare, Health Leaders, and a many other national and local publications. You can get more information about her health industry experience [here](#). If you need assistance with these or other compliance concerns, wish to inquire about arranging for compliance audit or training, or need legal representation on other matters please contact Ms. Stamer at (469) 767-8872 or via e-mail [here](#).

#### **Other Recent Developments**

If you found this information of interest, you also may be interested in reviewing some of the following recent Updates available online by clicking on the article title:

- [CMS Delegated Lead Responsibility For Development of New Affordable Care Act-Required Medicare Self-Referral Disclosure Protocol](#)
- [HHS announces Rules Implementing Tools Added By Affordable Care Act to Prevent Federal Health Program Fraud](#)
- [DMEPOS Suppliers Face 9/27 Deadline To Meet Tightened Medicare Standards](#)
- [Medicare Changing How It Pays For Outpatient Dialysis](#)
- [Rite Aid Agrees to Pay \\$1 Million to Settle HIPAA Privacy Case As OCR Moves To Tighten Privacy Rules](#)
- [HHS Invites Input On Medicaid Changes To Promote Children's Health Quality](#)
- [CMS Adopts ESRD Facility Prospective Payment System & Proposes New Quality Incentive Program](#)
- [CMS Rule Clarifies When Outpatient Services Subject to 3-Day Rule & Finalizes FY 2011 Inpatient Payment Rates](#)
- [New Affordable Care Act Mandated High Risk Pre-Existing Condition Insurance Pool Program Regulations Set Program Rules, Prohibit Plan Dumping of High Risk Members](#)
- [CMS Proposes Changes To Civil Monetary Penalty Rules For Nursing Homes](#)

#### **For More Information**

We hope that this information is useful to you. If you need assistance evaluating or responding to the Health Care Reform Law or health care compliance, risk management, transactional, operational, reimbursement, or public policy concerns, please contact the author of this update, Cynthia Marcotte Stamer, at (469) 767-8872, [cstamer@Solutionslawyer.net](mailto:cstamer@Solutionslawyer.net).

You can review other recent health care and internal controls resources and additional information about the health industry and other experience of Ms. Stamer [here](#). If you or someone else you know would like to receive future updates about developments on these and other concerns, please be sure that we have your current contact information – including your preferred e-mail – by creating or updating your profile at [here](#) or e-mailing this information [here](#). To unsubscribe, e-mail [here](#).