CLARIFICATION ON ELECTRONICALLY GENERATED PRESCRIPTIONS & VALIDITY OF ELECTRONIC SIGNATURES

At several recent MPhA Pharmacy Night events, members have been requesting clarification regarding electronically generated prescriptions for controlled substances, raising the question as to whether a prescription for a controlled substance is valid if electronically signed by a prescriber and transmitted via e-mail or fax. MPhA has sought clarification on this matter from both the DEA and the Minnesota State Board of Pharmacy. Both agencies have indicated that electronically generated controlled substance prescriptions must be printed out and manually signed by the provider. The rules cited by the agencies specifically pertaining to this issue are as follows:

“Except under limited circumstances, a pharmacist may dispense a Schedule II controlled substance only upon receipt of the original written prescription MANUALLY signed by the practitioner (21 U.S.C. 829, 21 CFR 1306.11). A pharmacist may dispense a Schedule III or IV controlled substance only pursuant to a written and MANUALLY signed prescription from an individual practitioner, which is presented directly OR TRANSMITTED VIA FAXSIMILE to the pharmacist, or an oral prescription, which the pharmacist promptly reduces to writing containing all of the information required to be in a prescription, except the signature of the practitioner (21 U.S.C. 829, 21 CFR 1306.21).”

The Board of Pharmacy clarification specifically states, “that the current rules are such that electronically generated controlled substance orders (for all schedules) that are electronically signed and sent to a pharmacy’s facsimile machine are not legally valid prescriptions. Nor are they legally valid if they are printed out and handed to the patient - unless the prescriber manually signs them.”

FDA ISSUES FINAL RULE REQUIRING TOLL-FREE NUMBER ON MEDICATION LABELING

Food and Drug Administration (FDA) has issued a final rule requiring the labeling for certain medications to include a toll-free number for patients to report side effects. The final rule confirms the interim final rule “Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products” and its requirement for the addition of a statement to the labeling for certain human drug products for which an application is approved under...
section 505 of the Federal Food, Drug, and Cosmetic Act. The statement must include a toll-free number and advise that the number is to be used only for reporting side effects and is not intended for medical advice. This final rule also affirms the interim final rule’s addition of a new part 209 to the regulations requiring distribution of the side effects statement. This final rule implements provisions of the Best Pharmaceuticals for Children Act (Public Law 107-109) and the Food and Drug Administration Amendments Act of 2007. The final rule is effective November 28, 2008, and the compliance date is July 1, 2009.

PRESIDENT BUSH SIGNS RYAN HAIGHT ACT, CRACKS DOWN ON INTERNET DRUG OUTLETS

President Bush signed into law House of Representatives (HR) Bill 6353, the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 on October 15, 2008. Now known as Public Law No. 110-425, the new law amends the Controlled Substances Act to prohibit the delivery, distribution, or dispensing of controlled substances over the Internet without a valid prescription. The law defines "valid prescription" as one issued for a legitimate purpose by a practitioner who has conducted at least one in-person medical evaluation of the patient. The legislation also adds definitions to the Controlled Substances Act relating to online pharmacies and the issuance of prescriptions over the Internet, imposes registration and reporting requirements on online pharmacies, and increases criminal penalties involving Schedule III, IV, and V controlled substances. The law also authorizes states to apply for injunctions or obtain damages and other civil remedies against online pharmacies that are deemed a threat to state residents.

METHAMPHETAMINE PRODUCTION PREVENTION ACT OF 2008 SIGNED INTO LAW

President Bush signed into law Senate (S) Bill 1276, the Methamphetamine Production Prevention Act of 2008, on October 14, 2008. Now known as Public Law No. 110-415, the legislation revises the logbook requirements of the federal Combat Methamphetamine Epidemic Act, enacted in 2006, which limits the amount of methamphetamine precursor drugs, such as pseudoephedrine, that a patient can buy and requires pharmacies to keep written or electronic logbooks recording each purchase of the drugs. The new law changes the earlier act to facilitate the use of electronic logbooks instead of written logbooks and provides grants to accomplish this goal. The new system is intended to provide law enforcement with easier access to information and streamline recordkeeping requirements for pharmacies.

BE A PART OF THE UPLAN MTM PHARMACISTS NETWORK

The University of Minnesota is pleased to announce that beginning in Spring 2009, the University of Minnesota Health Plan (UPlan) will begin reimbursing pharmacists to provide Medication Therapy Management services to its members. Pharmacy providers are being recruited from throughout the state to participate in the UPlan MTM Pharmacists Network. Your medication therapy expertise is vital to this effort!

UPlan members will be eligible to participate in the MTM program if they take four or more medications for chronic conditions. Copay waivers will be included in the program to incentivize participation.

You are qualified to be an MTM pharmacist in the UPlan network if you have an active pharmacy license and received a pharmacy degree in 1996 or later. If you graduated before 1996, completion of an approved MTM course will qualify you.

To request more information on becoming an UPlan MTM Pharmacist, including an enrollment form, please contact the UPlan MTM Benefit Program office at 612-625-0001, or balt0012@umn.edu. In addition, please see our developing website at: www.umn.edu/ohr/benefits/pharmacy/mtmproviders

2009 MEDICARE PART D PLANS

The Medicare Rx Access Network of Minnesota, the Center of Medicare and Medicaid Services (CMS), and the Senior LinkAge Line are spreading the word throughout the state of Minnesota about the upcoming open enrollment for the Medicare Part D Prescription Drug coverage. Many plans in Minnesota are changing this year and it is important to get the message out to Medicare Beneficiaries and their caregivers that their Medicare Part D plan should be reviewed to make sure it will still be the best plan for them in 2009. Plans that may have worked for beneficiar-
ies in the past may not cover the same medications, may have higher monthly premiums, may have different pharmacy networks, or may not offer coverage in the coverage gap as it did in the past.

The Senior LinkAge Line wants to work with pharmacies to provide outreach and enrollment assistance to their customers. If your pharmacy is interested in scheduling a time for Senior LinkAge Line staff and volunteers to help answer customer questions and make sure they have accurate information about their Medicare Part D plan, please call 1-800-333-2433 (Senior LinkAge Line).

We also encourage all pharmacists to give Medicare beneficiaries the Senior LinkAge Line telephone number in case they have any specific question or need additional help.

MPhA has posted documents online under the Pharmacists Resource link for pharmacists to use in assisting patients with their questions on open enrollment for Medicare Part D.

**MPhA FALL JOURNAL AVAILABLE ONLINE**

The Fall journal has shipped, but if you are waiting for your issue, start reading online! Association members can view the journal from the home page (after login!)

**SAVE THE DATE FOR MPhA’S MIDWINTER CONFERENCE**

**January 24-25, 2009**

The Depot • Minneapolis, MN

Join us for our first event of the year! Once again at The Depot, this event offers a wonderful opportunity to network, learn, and share in the mission of our association and foundation.

Sessions include: Good to Great - Key Concepts to Transform Your Practice, Sharing Your Experience via Abstracts and Posters, Childhood Leukemia, What Special Needs Families Want Health Professionals to Know, and Providing Equitable Care Amidst Growing Diversity.

The Minnesota Pharmacists Foundation will hold a causal Beer Tasting Dinner Saturday evening - the perfect way to relax and have fun after a day full of CE!

All Academies and Districts will also be meeting to elect their leadership.

Watch your mail for a full listing of sessions and additional information and make it your resolution to attend!