



1201 L Street, NW, Washington, DC 20005-4046
Main Telephone: 202-842-4444
Main Fax: 202-842-3860 2nd Main Fax: 202-842-3924
Writer's Telephone: 202-898.6307
Writer's E-Mail: sfitzler@ahca.org
www.ahca.org

Robert Van Dyk
CHAIR
Van Dyk Health Care
Ridgewood, NJ

Neil Pruitt, Jr.
VICE CHAIR
UHS-Pruitt Corporation
Norcross, GA

Rick Miller
IMMEDIATE PAST CHAIR
Avamere Health Services
Wilsonville, OR

Leonard Russ
SECRETARY/TREASURER
Bayberry Care Center
New Rochelle, NY

Fran Kirley
EXECUTIVE COMMITTEE LIAISON
Nexion Health
Sykesville, MD

Orlando Bisbano, Jr.
AT-LARGE MEMBER
Orchard View Manor Nursing &
Rehabilitation Center
East Providence, RI

Lane Bowen
AT-LARGE MEMBER
Kindred Healthcare
Louisville, KY

William Council, III
AT-LARGE MEMBER
Advocat Inc.
Brentwood, TN

Phil Fogg, Jr.
AT-LARGE MEMBER
Marquis Companies
Milwaukie, OR

Robin Hillier
AT-LARGE MEMBER
Lake Point Rehab & Nursing
Center
Conneaut, OH

Richard Kase
AT-LARGE MEMBER
Cypress Health Care Management
Sarasota, FL

Ted LeNeave
AT-LARGE MEMBER
American HealthCare, LLC
Roanoke, VA

Gary Kelso
NOT FOR PROFIT MEMBER
Mission Health Services
Huntsville, UT

Nicolette Merino
NCAL MEMBER
Avamere Health Services
Wilsonville, OR

Steve Ackerson
ASHCAE MEMBER
Iowa Health Care Association
West Des Moines, IA

Gail Rader
ASSOCIATE BUSINESS MEMBER
Care Perspectives
Phillipsburg, NJ

Mark Parkinson
PRESIDENT & CEO

January 12, 2011

Drug Enforcement Administration
Attention: DEA Federal Register Representative/ODL
8701 Morrissette Drive
Springfield, VA 22152

RE: Docket No. DEA-316
Submitted electronically at <http://www.regulations.gov>

Dear DEA Representative:

The American Health Care Association and National Center for Assisted Living (AHCA/NCAL) is pleased to respond to the Drug Enforcement Administration's (DEA's) request for comments, which was published in the *Federal Register* on December 22, 2010 (75 *Federal Register* 245, RIN 1117-AB18) on "Procedures for the Surrender of Unwanted Controlled Substances by Ultimate Users."

The nation's largest association representing more than 11,000 non-profit and proprietary nursing facilities, assisted living residences, post-acute care centers, and homes for people with developmental disabilities, our membership cares for millions of America's seniors and people with disabilities. Since the patients we care for often require multiple prescription drug medications – averaging nine medications per day – we fully understand that safe handling of prescription medications and appropriate disposal of unused medications is a significant responsibility.

AHCA/NCAL appreciates DEA's efforts in reaching out to key stakeholders and the American public in the development of regulations implementing the *Secure & Responsible Drug Disposal Act of 2010*, especially because disposal of prescription drugs can affect our communities, as well as the environment we all share.

Commitment to Safe Handling & Disposal of Prescription Drugs

Safe handling of prescription drug medications – ensuring patients' medications are not tampered with, nor diverted for other uses – is an essential part of providing quality long term and post-acute care. Because the patients we care for often need a variety of prescription medications to manage multiple comorbidities or severe post-surgical pain, long term care facilities are especially attuned to the management of Schedule II controlled substances.

In addition to patient safety issues, providers are concerned about polluting waste water and ground water resulting from seepage of pharmaceutical wastes from dumping sites. Even so, it is important to understand that the long term care sector is only a small part of our nation's overall health care system, and as such, long term care facilities generate far less drug waste than hospitals or individuals living at home. As we noted in our comments to the Environmental Protection Agency (EPA) on the addition of pharmaceuticals to its *Universal Waste Rule*, the majority of pharmaceutical drugs are taken by people in their own homes or communities, and not those cared for in institutional settings. When analyzing the amount of drugs found in ground water and waste water systems, it is important to consider that most drugs are metabolized by the body before being excreted and that some drugs may be excreted by the kidneys without being metabolized first.

Current State of Drug Disposal

Proper disposal of pharmaceutical waste represents a major challenge due to an inconsistent web of federal and state rules and restrictions, which governs the disposal of unused pharmaceuticals, including controlled substances.

Currently, unused controlled substances are destroyed in a long term care facility by a licensed medical professional in accordance with state pharmacy regulations. Many states allow facilities to return Schedule III – V drugs (non-controlled prescription drugs) to the pharmacy for disposal. Some state regulations allow unused and unwanted medications to be incinerated. Other states require medications to be destroyed in the facility and flushed into the sewer; however, certain states prohibit this form of disposal, which leaves facilities with no disposal options for controlled substances. The most common disposal practice for Schedule II drugs is to flush controlled substances according to state guidelines when the pharmacist visits the facility with the Director of Nursing or a nurse designee present.

Providers Support a National, Consistent Approach to Pharmaceutical Waste Disposal

As AHCA/NCAL has testified before the U.S. Senate Special Committee on Aging and other federal agencies, the inconsistent web of federal and state rules and restrictions governing the disposal of unused pharmaceuticals, including controlled substances, is both complex and confusing. While we welcome authoritative guidance that could direct our membership to improve disposal practices and compliance with applicable laws, the marked difference in how different care settings acquire and manage pharmaceuticals makes development of such guidance even more challenging.

To achieve DEA's goal of developing regulations that implement the *Secure & Responsible Drug Disposal Act of 2010* without creating new avenues for diversion, AHCA/NCAL encourages DEA to work cooperatively with other federal and state agencies and key stakeholder groups on a national strategy for defining and managing unused and outdated pharmaceuticals by all consumers and end users. Such a strategy

should allow for a single system for disposal of unwanted or outdated pharmaceuticals that includes both controlled substances and other medications.

AHCA/NCAL Recommendations

We know from our state affiliates that multiple state agencies need to work together on drug-related policy issues. These agencies range from those focused on pollution control, public works (i.e., municipal water treatment plants) and waste management to the State's health department, aging services agency, board of pharmacy and local police departments. Borrowing from our affiliates' experiences, AHCA/NCAL would suggest DEA reach out to the following agencies, which have some jurisdiction or input into overall prescription drug policy, including: the Department of Health & Human Services (HHS) – and the Centers for Medicare & Medicaid Services (CMS) in particular – the Federal Drug Administration (FDA), The White House Office of National Drug Control Policy (ONDCP), the Department of Veterans Affairs (VA), Department of Defense (DoD), and State Medicaid Agencies. By working together to resolve existing differences and barriers, DEA would be better positioned to develop regulations that provide a clear, consistent standard for all drugs.

In addition to working collaboratively with other federal and state agencies, AHCA/NCAL strongly urges DEA to work with health care providers. Long term care providers, in particular, have a variety of protocols in place that make drug diversion more difficult than in the ambulatory care setting. We respectfully suggest that DEA might gain insights that would aid the agency in its efforts to curtail teen prescription drug abuse by working cooperatively with providers, who can share best practices and protocols for dealing with controlled substances and other prescription medications.

Since myriad agencies and entities are already involved in the regulations that govern drug disposal in nursing facilities, AHCA/NCAL recommends that DEA pilot test several methods for drug disposal. In considering potential community "take back" sites, it is important to evaluate a site's capacity to process the volume of drugs that may be dropped off, and/or any legal or regulatory requirements that such a site might need. The kinds of programs that DEA might consider piloting could include on-site disposal methods; a program where all unused drugs are mailed to an approved entity for appropriate disposal; a reverse distributor program that collects unused controlled substances for disposal; and/or a community "take back" program that would allow long term care facilities and other providers to donate (instead of destroying) unused, properly packaged medication for community programs for the needy.

Conclusion

Americans are living longer and our nation's aging population is growing. In the face of these demographics, it is more important than ever to provide guidance for safe handling and appropriate disposal of prescription drug medication – guidance that must reflect the realities of current medical practice and the necessary system of communication that occurs across care settings.

Certainly, long term care professionals understand and support the DEA's role in preventing the diversion of controlled pharmaceuticals. In fact, DEA's stated goal in bringing narcotics and other drugs under legal control is to ensure that these "controlled substances" are readily available for medical use.¹ While we support DEA's efforts to prevent the sale or theft of prescription medications to drug dealers or abusers and other types of drug diversion, we remain perplexed by outdated rules and regulations that fail to take into account patients' needs and current medical practice.

We welcome the opportunity to work with DEA on developing rules that address the needs of our patients while maintaining the level of control over controlled substances that DEA expects and requires, and we thank you for the opportunity to offer these comments.

Sincerely,



Sandra Fitzler, RN
AHCA Senior Director of Clinical Services

cc: Mark W. Caverly
Chief, Liaison & Policy Section, DEA Office of Diversion Control

¹U.S. Department of Justice (DOJ) Drug Enforcement Administration (DEA) Office of Diversion Control Program Description of DEA Diversion of Controlled Pharmaceuticals, Retrieved March 22, 2010 from http://www.deadiversion.usdoj.gov/prog_dscrpt/index.html