

United States Senate

SPECIAL COMMITTEE ON AGING

WASHINGTON, DC 20510-6400

(202) 224-5364

October 19, 2009

The Honorable Eric Holder
Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, DC 20530

Dear Attorney General Holder:

While we recognize the importance of preventing the theft and diversion of prescription drugs in residential care settings, it has come to our attention that significant numbers of long-term care and hospice patients may not be receiving much-needed pain relief and other medications subject to the Controlled Substances Act (CSA) in a timely manner. The delays appear to be occurring in response to the Drug Enforcement Administration's (DEA) recently stepped-up enforcement of its drug diversion authorities in certain parts of the country, and the ensuing disruption of well-established medication coordination protocols. Based on our review of the legal framework governing long-term care patients' access to DEA-regulated medications, we believe Congress should consider modifying the CSA as it applies to this unique care context.

As presently written, the CSA fails to recognize how prescribing practitioners and the nurses who work for long-term care facilities and hospice programs actually order prescription medications. In post-acute, long-term care and hospice settings, a facility or hospice nurse (much like a hospital nurse) routinely acts as the "agent" of the treating physician by transcribing the physician's medication orders and transmitting them to the pharmacy, typically a pharmacy that contracts with the facility or program to serve its patients' medication needs. In order to comply with the CSA's recordkeeping requirements, however, the pharmacy may not rely upon these routine medication orders. Instead, the pharmacist must locate and communicate with the prescribing practitioner in person and obtain a separate, signed "hard copy" prescription from the prescriber before the pharmacy can dispense the controlled medication.

It is important to understand that providers caring for the frail elderly and terminally ill coordinate care in a very different environment than providers who serve patients in ambulatory or inpatient settings. According to the American Medical Directors Association, 40 percent of physicians who see patients in long-term care settings do not have an office practice, and those who maintain some form of office practice are only in their offices on a part-time basis. These practitioners rely upon nurses to submit their medication orders, including those subject to controls under the CSA, to the appropriate pharmacy. In most cases, because of the varied settings for these physicians' practices (which include seeing their patients in nursing homes, assisted living facilities, continuing care retirement centers, and hospice programs), and the high volume and variety of

medications needed by this patient population, it is difficult for practitioners to respond promptly to a pharmacy's faxes and phone calls requesting additional documentation for each CSA medication order.

It is our understanding that, for a number of years, the DEA heard concerns from advocates for long-term care residents and their providers that the CSA legal framework is ill-suited to the unique needs of this patient population and the practice protocols of those who provide their care. These concerns have substantial implications for the health of this most vulnerable patient group, as well as the cost of care. For example, delays in access to medically indicated prescription medicines can lead to adverse health outcomes and unnecessary re-hospitalizations, not to mention needless suffering. Moreover, long-term care providers are legally obligated, under the Nursing Home Reform Act, to provide residents with timely access to medically necessary medications and provide prompt relief of pain. A facility failing to meet these obligations can be sanctioned by the Centers for Medicare and Medicaid Services for deficient quality of care and violation of patients' rights. Yet the statutory and regulatory changes that would ameliorate this situation, and resolve conflicting compliance imperatives remain largely unchanged since 1994, when the DEA began to permit submission of long-term care prescriptions via facsimile.

Accordingly, we have prepared the enclosed draft legislation, which we believe strikes the appropriate balance between the legitimate law enforcement interest in preventing diversion and maintaining adequate controls, and the urgent needs of frail long-term care patients to prompt access to medically necessary prescription medicines.

We would appreciate your review and comment on the enclosed legislative draft within twenty days of this letter. In addition, we would appreciate your views on whether and how the pending e-prescribing rule would facilitate the timely and appropriate dispensing of controlled drugs to patients in long-term care settings, and your timetable for publication of a final rule. We also seek your input on whether additional regulatory changes are needed to ensure that these most vulnerable of patients receive timely access to vital medications.

Please contact Kristine Blackwood of the Committee's staff on (202) 224-5364 should you have any questions regarding this matter.

We look forward to working with you on this urgent issue.



Chairman
Herb Kohl

Sincerely,



U.S. Senator
Sheldon Whitehouse

<Enclosure>

cc:

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services

111TH CONGRESS
1ST SESSION

S. _____

To improve long-term care patients' access to medically necessary controlled substances.

IN THE SENATE OF THE UNITED STATES

_____ introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To improve long-term care patients' access to medically necessary controlled substances.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Long-Term Care Pa-
5 tients' Access to Medically Necessary Controlled Sub-
6 stances Act of 2009".

7 **SEC. 2. AMENDMENTS TO THE CSA.**

8 (a) AGENT.—Section 102(3) of the Controlled Sub-
9 stances Act (21 U.S.C. 802(3)) is amended by—

10 (1) inserting "(A)" after "(3)"; and

1 (2) inserting at the end the following:

2 “(B)(i) The term includes a licensed health care
3 professional who is authorized to act on behalf of the
4 practitioner.

5 “(ii) For purposes of this subparagraph, a li-
6 censed nurse in a licensed long-term care facility,
7 hospice, or home health agency shall be deemed to
8 be a practitioner’s agent, if the licensed nurse is act-
9 ing—

10 “(I) lawfully within the scope of his or her
11 license; and

12 “(II) in accordance with written policies
13 and procedures adopted by the long-term care
14 facility, hospice, or home health agency that de-
15 fine the agency relationship and specify the du-
16 ties and responsibilities of a practitioner’s
17 agent.”.

18 (b) **LAWFUL ORDER.**—Section 102(10) of the Con-
19 trolled Substances Act (21 U.S.C. 802(10)) is amended
20 by—

21 (1) inserting “(A)” after “(10)”; and

22 (2) inserting at the end the following:

23 “(B) In this paragraph, the term ‘lawful order’
24 shall include a medication order entered on the chart
25 or a medical record of a patient or resident receiving

1 long term care, hospice, or home health services by
2 a practitioner or his or her designated agent, if it
3 contains—

4 “(i) the full name of the patient;

5 “(ii) the date of issuance;

6 “(iii) the name, strength, and dosage form
7 of the drug prescribed;

8 “(iv) directions for use; and

9 “(v)(I) if written, the prescribing practi-
10 tioner’s signature or the signature of the practi-
11 tioner’s agent (including the name of the pre-
12 scribing practitioner), provided that the practi-
13 tioner countersigns the patient’s medication
14 order within the time period prescribed by law;
15 or

16 “(II) if electronically submitted, the pre-
17 scribing practitioner’s electronic submitted sig-
18 nature or the prescribing practitioner’s elec-
19 tronic or digital signature.”.

20 (c) PRESCRIPTIONS.—Section 309 of the Controlled
21 Substances Act (21 U.S.C. 829) is amended by inserting
22 at the end the following:

23 “(e) Nothing in this section shall be construed to pro-
24 hibit a pharmacist from preparing or transmitting a writ-
25 ten prescription for the signature of the practitioner.”.