U. S. Department of Justice
Drug Enforcement Administration
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Springfield, Virginia 22152

www.dea.gov

MAY 0 3 2012

Eric A. Dubelier, Esq.
Reed Smith LLP
1301 K Street, N.W.
Suite 1100 - East Tower
Washington, D.C. 20005-3373

Dear Mr. Dubelier:

This letter responds to your October 25, 2010, correspondence to Mr. Harry Matz as well as ongoing communications with the United States Attorney's Office for the Northern District of Ohio regarding your client's, Omnicare, Inc. (Omnicare), proposed "reminder letters" for prescribing practitioners. (See enclosed attachments A-1, A-2, B-1, B-2, C-1, and C-2).

The Drug Enforcement Administration (DEA) recognizes the importance of providing medications to patients residing in long-term care facilities in a timely and efficient manner. DEA also recognizes that these patients are often frail with multiple illnesses. It is therefore most important that any attempt to streamline this process does not diminish the doctor-patient relationship or otherwise weaken the quality of care for the frail and infirm. It is also important to ensure that any use of such letters is done so in conformity with all local, state, and federal laws and regulations.

One of the most important principles underlying the Controlled Substances Act (CSA) and its implementing regulations is that every prescription for a controlled substance must be predicated on a determination by an individual practitioner that the dispensing of the controlled substance is for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. 21 C.F.R. §1306.04(a) and *United States v Moore*, 423 U.S. 122 (1975). Therefore, the use of any "reminder letter" such as those developed by Omnicare (see attachments A-1, A-2, B-1, B-2, C-1, and C-2) must comply with this requirement.

Each of the attached letters contains a pre-printed form for use by prescribing practitioners. Each of the attachments, however, is designed for different circumstances. Attachments A-1 and A-2 notify prescribers that a previously authorized controlled substance prescription is about to expire and asks the practitioner whether he or she wishes to issue a new prescription for the patient. The top of these two letters each provides information such as the patient's name, date of birth, address, and previously prescribed medication. These letters instruct the prescriber to prepare and fax a valid prescription to the pharmacy if the prescriber wishes to continue drug therapy for the patient. Attachments B-1 and B-2 are reminder letters for compliance with 21 CFR §1306.11(d)(4) after an emergency oral prescription has been issued by a practitioner to a pharmacy.

Attachments C-1 and C-2 are similar to B-1 and B-2; however, C-1 and C-2 contain pre-populated information within the "prescription" portion of the reminder letter. Unlike the letters identified as A-1, A-2, B-1 and B-2, DEA rejects the use of the letters identified as C-1 or C-2 by Omnicare for several reasons. As stated above, a practitioner may authorize a controlled substance prescription only after the prescribing practitioner determines that a prescription for a controlled substance is for a legitimate medical purpose and for a specific patient. Accordingly, a pharmacy may not initiate a reminder letter to a prescribing practitioner

that provides a partially or fully pre-populated form for the prescribing practitioner because the practitioner has not yet made the determination, in the usual course of professional practice, that there is a legitimate medical purpose for the prescription. In addition, the pharmacy may not be characterized as the prescribing practitioner's agent for purposes of preparing the prescription because the regulations require the practitioner to instruct his or her authorized agent as to the required elements of a valid prescription, not *vice versa.*

While the core responsibilities pertaining to prescribing controlled substances may not be delegated to anyone other than the prescribing practitioner, an individual practitioner may authorize an agent to perform a limited role in preparing a prescription for the practitioner's signature. 21 C.F.R. § 1306.05(f). An authorized agent may prepare a controlled substance prescription only based upon the instructions of the prescribing practitioner as to the required elements of a valid prescription. 21 C.F.R. §§ 1306.04(a), 1306.05(a), (f). Thus, the practitioner must *first* determine that a prescription for a controlled substance is for a legitimate medical purpose; then, the practitioner may authorize an agent to prepare the prescription and must instruct the agent as to the required elements of the prescription. The CSA defines an "agent" as "an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser." 21 U.S.C. § 802(3). Establishment of an agency relationship, consistent with the CSA, is guided by general precepts of the common law of agency.

Finally, to safeguard the integrity of the prescription process, DEA regulations establish a check and balance by imposing independent responsibilities on DEA registrants. DEA regulations specify that pharmacists have a corresponding responsibility with practitioners for the proper prescribing and dispensing of controlled substances and must ensure that prescriptions for controlled substances conform in all essential respects to the law and regulations. 21 C.F.R. §§ 1306.04(a) and 1306.05(f).

I hope this clarifies a pharmacy's responsibilities with regard to initiating "reminder letters" and pre-populating authorization forms for prescribers. Note that the comments herein only speak to the matter of pre-populating authorization forms for prescribers. Should you have any questions or require further clarification, please contact Section Chief John Partridge, Liaison Section, at (202) 307-7874.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

Attachments: as stated

11/9/2011

A-1

DEA#
PH#
FAX#

REQUEST FOR CIII-V CONTINUANCE OF THERAPY PRESCRIPTION

DEAR PRACTITIONER

The current prescription for your patient has no refills remaining or is about to expire. If you want to continue therapy for your patient indicated below, please prepare and fax a valid signed written prescription to the pharmacy, or authorize a verbal prescription directly to the pharmacist. The prescription must contain all required elements of a controlled substance prescription as per 21 CFR 1306.05.

Pursuant to 21 CFR 1306.04(a), a prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by a practitioner in the usual course of professional practice.

PATIENT:
ADDRESS:

PAT ID:
DOB:

MEDICATION: LORAZEPAM 0.5MG TABLET

DIRECTIONS: TAKE 1 TABLET ORALLY EVERY 6 HOURS AS NEEDED FOR ANXIETY

*** Valid controlled substance prescriptions must contain all of the required elements of a prescription listed below, along with your signature. Controlled substance prescriptions cannot be dispensed if any information listed below is incomplete. ***

Date: _____
Patient Full Name: _____
Patient Full Address: _____
_____

Medication Name/Strength: _____
Dosage Form: _____
Quantity Prescribed: _____ (numeric)
_____ (alpha)
Directions for use: _____
_____
Number of Refills: _____

Practitioner Name: _____
Practitioner Full Address: _____
_____
Practitioner DEA Number: _____
Practitioner Signature: _____

11/9/2011

A-2

DEA#
PH#
FAX#

REQUEST FOR CII CONTINUANCE OF THERAPY PRESCRIPTION

DEAR PRACTITIONER

The current prescription for your patient is about to expire. If you want to continue therapy for your LTCF patient indicated below, please prepare and fax a valid signed written prescription to the pharmacy. The prescription must contain all required elements of a controlled substance prescription as per 21 CFR 1306.05.

Pursuant to 21 CFR 1306.04(a), a prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by a practitioner in the usual course of professional practice.

LTCF PATIENT: PAT ID:
ADDRESS: DOB:

MEDICATION: MS CONTIN 30MG TABLET SA

DIRECTIONS: TAKE 1 TABLET ORALLY EVERY 12 HOURS FOR PAIN

*** Valid controlled substance prescriptions must contain all of the required elements of a prescription listed below, along with your signature. Controlled substance prescriptions cannot be dispensed if any information listed below is incomplete. ***

Date: _____
Patient Full Name: _____
Patient Full Address: _____
_____

Medication Name/Strength: _____
Dosage Form: _____
Quantity Prescribed: _____ (numeric)
_____ (alpha)
Directions for use: _____
_____

Practitioner Name: _____
Practitioner Full Address: _____
_____
Practitioner DEA Number: _____
Practitioner Signature: _____

B-1

Practitioner Name and Address

DEA Number
Phone
Fax

Dear Practitioner
This medication has already been dispensed either from the contingency box or as an emergency supply as per your verbal authorization for the LTCF patient listed below. Federal law requires that a valid written and signed prescription be delivered to the pharmacy or be postmarked within 7 days. The pharmacy is also required to notify DEA if any prescriber fails to comply with this law. Please prepare a valid signed and written prescription with all of the required information listed below.
It is especially important to document the written prescription with the date of the verbal authorization for emergency dispensing and to also date the written prescription at the time of signature.
If you have any questions or concerns, please contact the pharmacy at 215-444-1212.

LTCF patient:

RX #

Unit/Rm/Bed
DOB
Pat ID

Date of Authorization for Emergency Dispensing:	07/26/2011
Medication:	OXYCODONE/APAP 5-325MG TABLET
Qty Authorized:	5 (FIVE) TABLET
Directions:	TAKE 1 TAB BY MOUTH EVERY 4 HOURS AS NEEDED FOR BACK PAIN

Valid controlled substance prescriptions must contain all of the required elements of a prescription listed below, along with your signature.

Date of Authorization for Emergency Dispensing			
Patient Full Name			
Patient Full Address	Street Address		
	City	State	Zip Code
MEDICATION name strength dosage/form			
Quantity Authorized (numeric)		Quantity Authorized (alphabetical)	
Directions for use			
Practitioner Full Name			
Practitioner Full Address	Street Address		
	City	State	Zip Code
Signature of Practitioner	Substitution Permissible	Dispense As Written	
Date signed		DEA Number	

DEA#
PH#
FAX#

DEAR PRACTITIONER
This medication has already been dispensed either from the contingency box or as an emergency supply as per your verbal authorization for the LTCF patient listed below. Federal law requires that a valid written and signed prescription be delivered to the pharmacy or be postmarked within 7 days. The pharmacy is also required to notify the DEA if any practitioner fails to comply with this law. Please prepare a valid written, signed prescription with all of the required information listed below.

It is especially important to document the written prescription with the date of the verbal authorization for emergency dispensing and to also date the written prescription at the time of signature.

PATIENT:
ADDRESS:

PAT ID :
RX# :
DOB :

DATE OF AUTHORIZATION
FOR EMERGENCY DISPENSING: 11/9/2011
MEDICATION: OXYCODONE/APAP 5-325MG TABLET
QTY: 5 (Five) TABLET
DIRECTIONS: TAKE 1 TABLET ORALLY EVERY 6 HOURS
AS NEEDED (DX: BACK PAIN) *VERBAL*

*** Valid controlled substance prescriptions must contain all of the required elements of a prescription listed below, along with your signature.***

Date of Authorization for Emergency Dispensing: _____
Patient Full Name: _____
Patient Full Address: _____
_____

Medication Name/Strength: _____
Dosage Form: _____
Quantity Prescribed: _____ (numeric)
_____ (alpha)
Directions for use: _____
_____

Practitioner Name: _____
Practitioner Full Address: _____
_____
Practitioner DEA Number: _____

Practitioner Signature: _____
Date Signed: _____

C-1

Practitioner Name and Address

DEA Number
Phone
Fax

Dear Practitioner
This medication has already been dispensed either from the contingency box or as an emergency supply as per your verbal authorization for the LTCF patient listed below. Federal law requires that a valid written and signed prescription be delivered to the pharmacy or be postmarked within 7 days. The pharmacy is also required to notify DEA if any prescriber fails to comply with this law. Please prepare a valid signed and written prescription with all of the required information listed below.
It is especially important to document the written prescription with the date of the verbal authorization for emergency dispensing and to also date the written prescription at the time of signature.
If you have any questions or concerns, please contact the pharmacy at 215-444-1212.

LTCF patient:

RX #

Unit/Rm/Bed
DOB
Pat ID

Date of Authorization for Emergency Dispensing:	07/26/2011
Medication:	OXYCODONE/APAP 5-325MG TABLET
Qty Authorized:	5 (FIVE) TABLET
Directions:	TAKE 1 TAB BY MOUTH EVERY 4 HOURS AS NEEDED FOR BACK PAIN

Valid controlled substance prescriptions must contain all of the required elements of a prescription listed below, along with your signature.

Date of Authorization for Emergency Dispensing	07/26/2011		
Patient Full Name			
Patient Full Address	Street Address		
	City	State	Zip Code
MEDICATION name strength dosageform			
Quantity Authorized (numeric)		Quantity Authorized (alphabetical)	
Directions for use			
Practitioner Full Name			
Practitioner Full Address	Street Address		
	City	State	Zip Code
Signature of Practitioner	Substitution Permissible	Dispense As Written	
Date signed		DEA Number	

C-2

DEA#
PH#
FAX#

DEAR PRACTITIONER
This medication has already been dispensed either from the contingency box or as an emergency supply as per your verbal authorization for the LTCF patient listed below. Federal law requires that a valid written and signed prescription be delivered to the pharmacy or be postmarked within 7 days. The pharmacy is also required to notify the DEA if any practitioner fails to comply with this law. Please prepare a valid written, signed prescription with all of the required information listed below.

It is especially important to document the written prescription with the date of the verbal authorization for emergency dispensing and to also date the written prescription at the time of signature.

PATIENT:
ADDRESS:

PAT ID :
RX# :
DOB :

DATE OF AUTHORIZATION
FOR EMERGENCY DISPENSING: 11/9/2011
MEDICATION: OXYCODONE/APAP 5-325MG TABLET
QTY: 5 (Five) TABLET
DIRECTIONS: TAKE 1 TABLET ORALLY EVERY 6 HOURS AS NEEDED (DX: BACK PAIN) *VERBAL*

*** Valid controlled substance prescriptions must contain all of the required elements of a prescription listed below, along with your signature.***

Date of Authorization for Emergency Dispensing: 11/9/2011
Patient Full Name: _____
Patient Full Address: _____
_____

Medication Name/Strength: _____
Dosage Form: _____
Quantity Prescribed: _____ (numeric)
_____ (alpha)
Directions for use: _____
_____

Practitioner Name: _____
Practitioner Full Address: _____
_____
Practitioner DEA Number: _____

Practitioner Signature: _____
Date Signed: _____