DHMH
Division of Drug Control

- Medication, Drugs and
- Controlled Dangerous Substance
- Safety in Assisted Living

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I would like to give you a little background about Division of Drug Control (DDC) and who we are.

- DDC is a small division within the Department of Health and Mental Hygiene (DHMH). We are 10-11 people in the unit.
- The division has a responsibility to ensure safety of Controlled Dangerous Substances (CDS).
- It also supports the Drug Enforcement Administration (DEA) in their investigations.
The small group of individuals comprising DDC perform a wide range of functions, as you can see. This includes processing the applications, printing the registration certificates, mailing and filing the completed applications. The remaining functions (inspections, record reviews, supporting DEA) are performed by the inspectors.
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Registration

- DDC processes registration of over 30,000 practitioners and establishments including:
  - Assisted Living Facilities
  - Long Term Care Facilities
  - Pharmacies
  - Hospitals/Clinics
  - Methadone & Drug/Alcohol Centers
  - Animal Shelters/Veterinarians
  - and others

Registration procedures takes up the bulk of time for the office staff—it is no easy task to keep up with the 30,000 plus registrations.

As you can see here, there are a wide variety of organizations who are required to go through the registration process. Registration is required by any individual or facility that handles controlled substances and the registrations are renewed every 2 years.
The COMAR is often considered “the bible” for running an ALF. It provides all the guidelines but unfortunately very little guidance on controlled drugs.
Registration with DDC is required by:
- CR 5-301 (a) which states:
  - “a person shall be registered by the Department before the person manufactures, distributes, or dispenses a controlled dangerous substance in the state”.

The requirement for registration is stated in several regulations. CR 5-301 is quoted here.
CR 5-101(k) which defines “dispense” as:

1. (1) to deliver to the ultimate user or the human research subject, or in accordance with the lawful order of an authorized provider.
2. (2) “Dispense” includes to prescribe, administer, package, label, or compound a substance for delivery.

It is further defined in CR 5-101 and in COMAR 10.07.14.02

Dispensing is described as the administering of a drug to the final party.
In other words, any facility in which controlled substances are administered to a resident is required by regulation to have a CDS registration issued by our office.
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Registration with DDC:

- COMAR 10.07.14.29 empowers an Assisted Living Facility to administer controlled dangerous substances (CDS) and it is therefore required to obtain a CDS Registration and comply with CR 5-301 which states “a person shall be registered by the Department before the person manufactures, distributes or dispenses a Controlled Dangerous Substance”.

Finally, COMAR 10.07.14.29 (which was recently published as the guide to Assisted Living Facilities) also indicates that registration is required.

Registration with the office allows you to legally administer CDS.
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Registration Process:
- Download application form from website: www.dhmh.state.md.us/drugcont
- Complete appropriate sections
- Make copy of OHCQ license
- Mail application, copy of OHCQ license and check for the appropriate fee ($120/2 years) to DDC.

The registration process is quite simple:
1. Obtain an application form. This can be obtained by accessing DDC’s website.
2. Complete the appropriate sections.
3. Return it to DDC along with a copy of your OHCQ license and a check for the appropriate fee.
4. It takes a week or two to process the application and to forward your registration certificate. The certificate is good for a period of 2 years.
5. Several months prior to the expiration of your registration you will receive a notice that it is time to renew it.

The registration cannot be done online (must be done via mail).
Visits may be done at any time and will not be announced. An inspector will appear and request to see the nurse in charge.
What do visits to Assisted Living Facilities accomplish?
- Determine if procedures being used are in the best interest of the resident’s well being.
- Determine if protection of CDS is adequate to prevent theft or diversion.
- Insure compliance with regulations.
- Provide opportunity to make recommendations for improvement where necessary.

What will the inspectors look at when they make a visit?
1. Procedures for the handling of CDS.
2. Security of CDS from theft or diversion.
3. Whether regulations are being followed.

The inspectors will also provide recommendations or suggestions concerning something you might not be doing or how you can do something better.

ALFs have a duty to provide the best care for their residents. The care should be compliant with regulations that deal with drug administration, drug storage, etc.
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- Inspections
  - Visits to Assisted Living Facilities began in April 2009.
  - Focus of visits are:
    - Verify Registration
    - Determine adequacy of storage of CDS to prevent theft/diversion
    - Verify access to CDS and record keeping
    - Destruction of CDS and reporting procedures

The focus of the visits are as indicated here. (A copy of the inspection sheet is in your packet.)

The verification is simple: either you have a certificate or you do not.

The inspectors verifies:
- that only those who are authorized have access to the CDS.
- that proper records are kept.
- proper destruction of CDS, due either to drug expiring or to discontinued order
Storage of CDS is high on the list for the inspectors. Insuring that CDS are not prone to theft and diversion is one of the inspector’s primary jobs.

The interpretation of double lock system creates variability. Second lock can be almost any type of lock. Recommendations as to the quality of the lock system might be made from inspector.

In your hand-out packet is a list of all of the commonly used drugs and their schedules (I-V).
- Schedule II are likely to cause abuse
- Schedule III could cause abuse but not as likely as schedule II

If you are not sure what schedule a drug is, I recommend to lock any scheduled drug under double lock.
Access

- COMAR 10.07.14 further states:
  - All staff who administer medications shall have completed the medication administration administration course that is taught by a registered nurse who is approved by the Maryland Board of Nursing.
  - AL manager shall document completion of the medication technician training of each staff member who administers medications.

It is also very important to know who has access to CDS. Someone must be accountable for the safety of these products and be knowledgeable concerning their administration. It may be necessary that the records of training are made available for the inspectors.
Accountability and Record Keeping

- Staff shall count and record controlled drugs, such as narcotics, before the close of every shift.
- The daily record shall account for all controlled drugs documented as administered on the MAR.

As required by COMAR 10.07.14, shift to shift counts of controlled drugs must be made and appropriate records of these counts must be maintained. This record is in addition to the MAR.

I suggest developing a form which shows the date, shift, column for any discrepancy noted, and space for two individuals to sign. Most places have a separate sheet in addition to the MAR where they keep track of controlled drugs – this is good practice.

Whenever the handling personnel changes, the drugs should be counted and signed for. There are some facilities that do not have normal shifts (e.g. 24hr live-in caregivers) but whenever there is a change in the shift, there should be a controlled drug count.
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- Destruction of CDS
  - COMAR 10.19.03.10 states:
    - Any registrant in possession of legally obtained CDS and desiring or required to dispose of any of these substances may ask the Division of Drug Control of the DHMH for authority and instructions to dispose of this substance.
    - In a facility registered to administer only, two members of the professional staff (administrator, nurse, pharmacist) may destroy controlled drugs on the premises.

There will be occasions when it is necessary to dispose controlled drugs: orders will be changed, orders will be discontinued, residents will be discharged etc. And you will be left holding these medications. How do you dispose of them?

The first thing you need to know is that CDS cannot be returned to the pharmacy. Regulations state that CDS may be destroyed on site when drugs are no longer need or they have been discontinued by the physician. It takes two people to witness and document the fact that the drugs are destroyed. This should be members of the professional staff (nurses, licensed administrators or visiting pharmacists) that are registered. If a person is not registered, they cannot legally destroy the drugs. It is recommended that a delegated nurse is one of these two people.
Since immediate destruction is not always possible, it may be necessary to hold the drugs until the appropriate people are available. Even though these drugs are no longer being used, they must be safeguarded until they can be destroyed. Accountability of these drugs is just as important as those you use every day. They can be counted along with the drugs you are using or they can be segregated and counted separately.

If the CDS are stored separately, an inventory must be maintained to insure their safety. I recommend that a destruction report is prepared and that each drug awaiting destruction is added to the report. This way when you are ready to destroy, the report is already prepared. The report can also serve as the inventory to help you account for the drugs until destruction takes place.
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Destruction Records

COMAR 10.19.03.10 further states:

A record of the disposal shall be recorded on a form to be supplied by the Division of Drug Control. A copy of this form is to be forwarded to the Division within 10 days of destruction.

The report should be mailed to the address on the form.

Once you are ready to destroy, a record that shows specific information (i.e. drug name, strength, quantity destroyed, date of destruction, persons responsible for destruction, how they were destroyed) must be prepared. Once destruction have taken place, a copy of the report must be sent to DDC within 10 days. You must keep a copy of the report on file in your facility for a period of at least 2 years. A copy of a destruction form is in your hand-out packet.
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What have inspections revealed?

- No CDS Registration
- Multiple facilities, separate OHCQ license, one CDS Registration
- No written Policy and Procedures for safety of controlled substances
- Schedule III CDS not under double lock
- Shift change counts not signed by on-coming and off-going individuals

Many facilities have not registered with DDC. If that is the case, the inspectors will then ask you to register. Every licensed facility must have its own registration certificate. If a person owns multiple facilities, each facility still needs its own registration.

Most smaller facilities do not have a policy and procedure for the safety of CDS.

Facilities are usually rigid about storing schedule II drugs, but they don’t seem to be that way with schedule III. This may be because they do not know what the schedule III drugs are. Since there will often be confusion about what schedule a drug is, a good rule is to keep any controlled drug under double lock.

Whenever you count the drugs, make a record of it!
Whenever there is a discrepancy in counting, the delegating nurse should be notified.

If the drug comes out of the blister pack, no matter if it came out in error, it needs to be destroyed. By putting unused drugs back in the blister pack and tape them up, there is a risk that the wrong drug gets put back.
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- Deficiencies Observed
  - Medication Cart keys not secured
  - Expired Medications being used
  - Necessary information missing from inventory sheets
  - Incidence of diversion

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Deficiencies Observed

Destruction Procedures
- Method of destruction
- Improper storage and control of medications awaiting destruction
- CDS being returned to the Pharmacy
- Destruction Report not prepared
- Copies of Destruction Reports not forwarded to DDC

There is a concern about the fact that medications are sometimes being destroyed by being put in the sewer system. It is advised not to do that. I recommend crushing the tablets, opening the capsules, adding a liquid and coffee grounds and then throwing them in the trash – do not just throw them away!

It is illegal to return CDS to the pharmacy.
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- DDC Website:
  www.dhmh.state.md.us/drugcont
- Contacts:
  - Fred Evans
    evansf@dhmh.state.md.us
  - Chandra Mouli
    moulic@dhmh.state.md.us

A copy of the letter sent to all ALFs concerning the requirement for registration is in your hand-out packet.

DDC doesn’t issue citations – they only issue advice and recommendations. If you have any questions about controlled drugs, do not hesitate to contact us.
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- THANK YOU

- QUESTIONS?