DEPARTMENT OF HEALTH SERVICES
Division of Care and Treatment Services
F-24277 (09/2016)

STATE OF WISCONSIN
42 CFR483.420(a)(2)
DHS 134.31(3)(o)
DHS 94.03 & 94.09
§§ 51.61(1)(g) & (h)

INFORMED CONSENT FOR MEDICATION

Dosage and / or Side Effect information last revised on 06/08/2017

Completion of this form is voluntary. If not completed, the medication cannot be administered without a court order unless in an emergency. This consent is maintained in the client's record and is accessible to authorized users.

Name – Patient / Client (Last, First MI)	ID Number	Living Unit	Date of Birth
,			

Name – Individual Preparing This Form	Name – Staff Contact	Name / Telephone Number – Institution

MEDICATION CATEGORY	MEDICATION	RECOMMENDED DAILY TOTAL DOSAGE RANGE	ANTICIPATED DOSAGE RANGE
Central Nervous System Stimulant	Cylert (pemoline)	3.75mg - 112.5mg	

The anticipated dosage range is to be individualized, may be above or below the recommended range but no medication will be administered without your informed and written consent.
Recommended daily total dosage range of manufacturer, as stated in *Physician's Desk Reference* (PDR) or another standard reference.
This medication will be administered ☐ Orally ☐ Injection ☐ Other – Specify:

1. Reason for Use of Psychotropic Medication and Benefits Expected (note if this is 'Off-Label' Use)
Include DSM-5 diagnosis or the diagnostic "working hypothesis."

2. Alternative mode(s) of treatment other than OR in addition to medications include
Note: Some of these would be applicable only in an inpatient environment.

☐ Environment and/or staff changes
☐ Positive redirection and staff interaction
☐ Individual and/or group therapy
☐ Rehabilitation treatments/therapy (OT, PT, AT)
☐ Treatment programs and approaches (habilitation)
☐ Use of behavior intervention techniques

Other Alternatives:

3. Probable consequences of NOT receiving the proposed medication are

Impairment of ☐ Work Activities ☐ Family Relationships ☐ Social Functioning

Possible increase in symptoms leading to potential

☐ Use of seclusion or restraint
☐ Limits on access to possessions
☐ Limits on personal freedoms
☐ Limit participation in treatment and activities
☐ Limits on recreation and leisure activities
☐ Intervention of law enforcement authorities
☐ Risk of harm to self or others

Other Consequences:

Note: These consequences may vary depending upon whether or not the individual is in an inpatient setting. It is also possible that in unusual situations, little or no adverse consequences may occur if the medications are not administered.

See Page 2

Client Initial _____ Date _____

4. Possible side effects, warnings, and cautions associated with this medication are listed below. This is not an all-inclusive list but is representative of items of potential clinical significance to you. For more information on this medication, you may consult further with your physician or refer to a standard text, such as the PDR. As part of monitoring some of these potential side effects, your physician may order laboratory or other tests. The treatment team will closely monitor individuals who are unable to readily communicate side effects in order to enhance care and treatment.

Continued – Possible side effects, warnings, and cautions associated with this medication.

Most Common Side Effects
Other more common side effects include: Blisters under the skin; flushing or redness of skin; loss of appetite; nervousness; sleeplessness; small, rounded bumps rising from the skin; stuffy nose; swelling at the site of patch application; trouble with sleeping; unable to sleep; unusually warm skin.

Less Common Side Effects
Less common side effects include dizziness; drowsiness; headache; increased irritability; mental depression; stomachache.

Rare Side Effects
Check with your doctor immediately if any of the following rare side effects occur: Dark urine; yellow eyes or skin.
Check with your doctor as soon as possible if any of the following side effects occur: Convulsions (seizures); hallucinations (seeing, hearing, or feeling things that are not there); nausea and vomiting; shortness of breath, troubled breathing, wheezing, or tightness in chest; skin rash; sores, ulcers, or white spots on lips or in mouth; swollen or painful glands; uncontrolled movements of eyes, tongue, lips, face, arms, or legs; unusual bleeding or bruising; unusual tiredness; vocal sounds you cannot control.
Other rare side effects include: Liver problems; slow growth in children.
Symptoms of overdose: Agitation; confusion; convulsions (seizures)—may be followed by coma; false sense of well-being; fast heartbeat; hallucinations (seeing, hearing, or feeling things that are not there); headache (severe); high blood pressure; high fever; large pupils; muscle trembling or twitching; restlessness; sweating; vomiting.

Caution
This medicine may cause some people to become dizzy or less alert than they are normally. Make sure you know how you react to this medicine before you ride a bicycle or do anything else that could be dangerous if you are dizzy or are not alert.

Warning
BLACK BOX WARNING
Because of its association with life threatening hepatic failure, pemoline should not ordinarily be considered as first line drug therapy for ADHD. Because pemoline provides an observable symptomatic benefit, patients who fail to show substantial clinical benefit within 3 weeks of completing dose titration, should be withdrawn from pemoline therapy.

Since pemoline's marketing in 1975, 15 cases of acute hepatic failure have been reported to the FDA. While the absolute number of reported cases is not large, the rate of reporting ranges from 4 to 17 times the rate expected in the general population. This estimate may be conservative because of under reporting and because the long latency between initiation of pemoline treatment and the occurrence of hepatic failure may limit recognition of the association. If only a portion of actual cases were recognized and reported, the risk could be substantially higher.

Of the 15 cases reported as of December 1998, 12 resulted in death or liver transplantation, usually within four weeks of the onset of signs and symptoms of liver failure. The earliest onset of hepatic abnormalities occurred six months after initiation of pemoline. Although some reports described dark urine and nonspecific prodromal symptoms (e.g., anorexia, malaise, and gastrointestinal symptoms), in other reports it was not clear if any prodromal symptoms preceded the onset of jaundice.

Treatment with pemoline should be initiated only in individuals without liver disease and with normal baseline liver function tests. It is not clear if baseline and periodic liver function testing are predictive of these instances of acute liver failure; however it is generally believed that early detection of drug-induced hepatic injury along with immediate withdrawal of the suspect drug enhances the likelihood for recovery. Accordingly, the following liver monitoring program is recommended: Serum ALT (SGPT) levels should be determined at baseline, and every two weeks thereafter. If pemoline therapy is discontinued and then restarted, liver function test monitoring should be done at baseline and reinitiated at the frequency above.

Pemoline should be discontinued if serum ALT (SGPT) is increased to a clinically significant level, or any increase ≥ 2 times the upper limit of normal, or if clinical signs and symptoms suggest liver failure.

The physician who elects to use pemoline should obtain written informed consent from the patient prior to initiation of pemoline therapy.

WARNING
Decrements in the predicted growth (i.e., weight gain and/or height) rate have been reported with the long-term use of stimulants in children. Therefore, patients requiring long-term therapy should be carefully monitored.

PATIENT CONSENT
My (son, daughter, ward)_____'s treatment with Cylert has been explained to me by Dr._____.
The following points of information, among others, have been specifically discussed and explained and I have had the opportunity to ask any questions concerning this information.
1. I, _____(Patient/Parent/Guardian's name), understand that Cylert is used to treat certain types of patients with the behavioral syndrome called attention deficit hyperactivity disorder (ADHD) and that I (my son/daughter/ward) am that type of patient. Initials:_____
2. I understand that there is a risk that I (my son/daughter/ward) might develop liver failure, which may result in death, while taking Cylert. I understand that this could occur even after long-term therapy. Initials:_____

3. I understand that I (my son/daughter/ward) should have blood taken to test liver function before Cylert is begun, and every two weeks from then on while taking Cylert. I understand that although the liver function tests may help detect if I (my son/daughter/ward) develop liver damage, it may do so only after significant, irreversible and potentially fatal damage has already occurred. Initials:____
4. I understand that if I (my son/daughter/ward) stop taking Cylert and then restart it at a later time (e.g., after summer vacation), I (my son/daughter/ward) should again have blood taken to test liver function before Cylert is restarted, and every two weeks from then on while taking Cylert. Initials:_____
5. I understand that I should immediately report any unusual symptoms to the doctor and should be especially aware of persistent nausea, vomiting, fatigue, lethargy, loss of appetite, abdominal pain, dark urine, or yellowing of the skin or eyes. Initials:_____

I now authorize Dr._____ to begin my (son/daughter/ward's) treatment with Cylert, or if treatment with Cylert has already begun, to continue this treatment.

_____ _____

SIGNATURE – Parent/Guardian Date Signed

_____ _____

Address Telephone Number

PHYSICIAN STATEMENT

I have fully explained to the patient (parent/guardian), _____ the nature and purpose of treatment with Cylert and the potential risks associated with that treatment. I have asked if he/she has any questions regarding this treatment or the associated risks and have answered these questions to the best of my ability.

_____ _____

SIGNATURE – Physician Date Signed

NOTE TO PHYSICIAN: It is strongly recommended that you retain a completed copy of this informed consent form in your patient's records. See PDR for an all-inclusive list of side effects.

By my signature below, I GIVE consent for the named medication on Page 1 and anticipated dosage range. My signature also indicates that I understand the following:

1. I can refuse to give consent or can withdraw my consent at any time with written notification to the institution director or designee. This will not affect my right to change my decision at a later date. If I withdraw consent after a medication is started, I realize that the medication may not be discontinued immediately. Rather, it will be tapered as rapidly as medically safe and then discontinued so as to prevent an adverse medical consequence, such as seizures, due to rapid medication withdrawal.
2. Questions regarding this medication can be discussed with the Interdisciplinary Team, including the physician. The staff contact person can assist in making any necessary arrangements.
3. Questions regarding any behavior support plan or behavior intervention plan, which correspond with the use of the medication, can be directed to the client's social worker, case manager, or psychologist.
4. I have the right to request a review at any time of my record, pursuant to § 51.30(4)(d) or § 51.30(5)(b).
5. I have a legal right to file a complaint if I feel that client rights have been inappropriately restricted. The client's social worker, case manager, or agency/facility client rights specialist may be contacted for assistance.
6. My consent permits the dose to be changed within the **anticipated dosage range** without signing another consent.
7. I understand the reasons for the use of the medication, its potential risks and benefits, other alternative treatment(s), and the probable consequences that may occur if the proposed medication is not given. I have been given adequate time to study the information and find the information to be specific, accurate, and complete.
8. This medication consent is for a period effective immediately and not to exceed fifteen (15) months from the date of my signature. The need for and continued use of this medication will be reviewed at least quarterly by the Interdisciplinary Team. The goal, on behalf of the client, will be to arrive at and maintain the client at the minimum effective dose.

SIGNATURES		**DATE SIGNED**
Client – If Presumed Competent to Consent/Parent of Minor/Guardian (POA-HC)	Relationship to Client ☐ Self ☐ Parent ☐ Guardian (POA-HC)	
Staff Present at Oral Discussion	Title	

Client / Parent of Minor / Guardian (POA-HC) Comments

As parent/guardian (POA-HC) was not available for signature, he/she was verbally informed of the information in this consent.

Verbal Consent

Obtained by – PRINT – Staff Name	Date Obtained	Written Consent Received ☐ Yes ☐ No
Obtained from – PRINT – Parent / Guardian (POA-HC) Name	Date Expires	Date Received