TITLE: E/M Table of Risk and Parenteral Controlled Substances

POLICY/PURPOSE:

In an effort to apply the definition of "parenteral controlled substances" consistently, the UF College of Medicine – Jacksonville Compliance Committee has determined that the Food and Drug Administration's list of "Controlled Substances" will be the source when determining whether a drug or substance is to be considered "Controlled."

The route of administration (whether actual or ordered) will determine whether the substance meets the definition below of "parenteral."

There are three elements of medical decision-making according to the Center for Medicare and Medicaid (CMS) *Documentation Guidelines for Evaluation and Management Services* (both 1995 and 1997 versions):

- the number of possible diagnoses and/or the number of management options that must be considered;
- the amount and/or complexity of medical records, diagnostic tests, and/or other information that must be obtained, reviewed and analyzed; and
- the risk of significant complications, morbidity and/or mortality, as well as comorbidities, associated with the patient's presenting problem(s), the diagnostic procedure(s) and/or the possible management options ("Risk").

To qualify for a given level of medical decision-making, two of the three elements above must be met.

One of these elements is Risk. To assist with determining the overall level of Risk, CMS developed a "Table of Risk" which is divided into three categories:

- Presenting Problem(s);
- Diagnostic Procedure(s) Ordered; and
- Management Options Selected.

The highest level of Risk in any one category (presenting problem(s), diagnostic procedure(s), or management option) determines the overall Risk.

When the management option selected under the Table of Risk is "parenteral controlled substances," a High level of overall Risk may be credited.

DEFINITIONS:

Controlled Substance – a schedule I, II, III, IV, or V drug or other substance.

Parenteral – substance administered/given by a route other than the alimentary canal.

PROCEDURE:

1. The Food and Drug Administration website provides schedules of Controlled Substances. Check the list of Controlled Substances via the FDA website.
2. If the drug/substance is a Schedule I, II, III, IV, or V then the drug/substance is considered "Controlled."
3. Determine whether the drug/substance is to be administered parenterally (check order) or was administered parenterally (review provider's note or nursing notes).
4. If the drug/substance was administered parenterally or if an order was written for the drug/substance to be administered parenterally and the drug/substance is considered "Controlled," a High level of overall Risk may be credited toward the level of medical decision-making.
5. If the drug/substance administered or to be administered is not a "Controlled Substance" or was not administered parenterally or was not ordered to be administered parenterally, then a High level of overall Risk may **not** be credited toward the level of medical-decision making for parenterally controlled substances. The medical record will need to be reviewed for other indications to determine the level of overall Risk.

REFERENCES:

The list of "Controlled Substances" may be accessed via the Food and Drug Administration website by clicking here.

This information is updated periodically. As such, the Office of Compliance advises that the website be accessed real-time, as needed, instead of referencing a previously downloaded list.

21 CFR 1308.

APPROVED BY: UF College of Medicine – Jacksonville Compliance Committee