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## State of Misconsin 2005 - 2006 LEGISLATURE

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## SENATE AMENDMENT 2, TO 2005 SENATE BILL 288

October 20, 2005 - Offered by Senator STEPP.

At the locations indicated, amend the bill as follows:

**1.** Page 3, line 22: delete that line and substitute:

"632.87 (6) (a) 1. Except as provided in subd. 2., in this subsection, "routine costs" means all health care services, items, and drugs that are typically provided in health care; all health care services, items, and drugs that are required solely for the provision of the health care service, item, or drug; the appropriate monitoring of the effects of the health care services, items, and drugs; the prevention of complications arising from the health care services, items, and drugs; and health care services, items, and drugs that are needed for reasonable and necessary care arising from the provision of the health care service, item, or drug.

2. "Routine costs" does not include the health care service, item, or investigational drug that is the subject of the trial; any services provided solely to satisfy data collection and analysis needs that are not used in the direct clinical

- management of the patient; any services, items, or drugs provided by the trial sponsors free of charge for any patient; or any services, items, or drugs that are eligible for reimbursement by a person other than the insurer, including the sponsor
- 4 of the trial.
- 5 (b) No policy, plan, or contract may exclude coverage for any routine costs".
- 6 **2.** Page 3, line 23: delete "service, item, or drug".
- 7 **3.** Page 3, line 23: delete "that is" and substitute "that are".
- 4. Page 3, line 24: delete the material beginning with "health care service,"
  and ending with "had it" on page 4, line 1 and substitute "routine costs had the
- 10 routine costs".
- **5.** Page 4, line 3: delete "(a)" and substitute "1.".
- 12 **6.** Page 4, line 4: delete "1." and substitute "a.".
- 13 **7.** Page 4, line 6: delete "2." and substitute "b.".
- **8.** Page 4, line 8: delete "3." and substitute "c.".
- **9.** Page 4, line 11: delete "4." and substitute "d.".
- 16 **10.** Page 4, line 13: delete "(b)" and substitute "2.".
- 17. Page 4, line 14: delete "1." and substitute "a.".
- 18 **12.** Page 4, line 16: delete "2." and substitute "b.".
- 19 **13.** Page 4, line 17: delete "3." and substitute "c.".
- 20 **14.** Page 4, line 18: delete "4." and substitute "d.".
- 21 **15.** Page 4, line 19: delete "5." and substitute "e.".
- 22 **16.** Page 4, line 21: after that line insert:

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- "3. The clinical trial is not designed exclusively to test toxicity or disease pathophysiology but has therapeutic intent.
  - 4. The clinical trial enrolls individuals with diagnosed disease rather than healthy individuals, except that if the clinical trial tests a diagnostic intervention it may enroll healthy individuals in order to have a proper control group.".

6 (END)