1/9/06

Phone conversation w/ Matthew & Laura

want quality "improvement" activity not review

subjects vs. purpose of review
look at /P1 list

move (2)(a)5. into activity — in (1)(d)

wants continuous, periodic, etc. in the draft

"structure" – beyond structure of a particular organization
structure of health care

said I would try to make "structure" & "process" subjects

(d) make sure clear as relates to one or more HCEs

---

(2)(a) 1.-6. who can do review
make sure if hosp reviews, doc is covered

define agent?

* a system owns hospitals and system personnel will

want to review all hospitals 1/9 (cont.)

"ad hoc" - look at dictionary def.

move last clause of (2)(a)(intro.) to QIA

who creates or collects records
- can it be anyone or need to be more specific

cover records presented by JCAHO to HCE — or is in 1

they are concerned everything will fall under ~~treatment~~ record exception

Cover notice to physician of upcoming review as conf.

LRB
Wisconsin Legislative Reference Bureau

Ryan, Robin

From: Stanford, Matthew [mstanford@wha.org]

Sent: Tuesday, January 10, 2006 8:54 AM

To: Ryan, Robin

Cc: Leitch, Laura

Subject: Quality Improvement Draft

Attachments: Quality Improvement Activity def.doc

Robin,
Thanks again for all of your work and help in getting this draft ready for Rep. Underheim. It is really appreciated. Pursuant to our discussion yesterday regarding the definition of quality review/quality improvement activity, I have attached some language that captures the intent of that discussion and that might be helpful to you as you draft that section to reflect a list of subjects rather than purposes as you had suggested.

After the teleconference yesterday, Laura and I thought of a couple of things that didn't get brought up but we wanted to give you a heads up on before this afternoon's meeting. The first issue is that there may need to be some tweaking of sections (3)(c) and (3)(e) depending on changes that we discussed yesterday to the substance of what is protected through (1)(d) and (2)(a). The other issue regards aggregation for public reporting. I know that yesterday we discussed in relation to (2)(a)6., how aggregation in some instances is a part of the quality improvement activity, but in some instances is used to further public reporting but might not fall into a definition of quality improvement activity. It is probably possible to address these two situations within the organization of quality improvement activity, but would it be beneficial for purposes of ease of use and clarity if public reporting had its own section? For hospitals considering engaging in a public reporting initiative, if all of the provisions regarding public reporting were in one spot in the statutes it would make it significantly easier for them to spot the issues and evaluate whether they should participate in a public reporting initiative. Is this something is possible within drafting context?

Again, the draft seems to be very close and Laura and I thank for your hard work on this. We will see you this afternoon.

Matthew Stanford
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1/10/06
From Matthew

a HCE concerning any of the following subjects

(d) "Quality improvement activity" means any monitoring of, or evaluation, review, study, assessment, investigation, recommendation, corrective action, or other action or process relating to any of the following, and may involve continuous, periodic, or a single data collection and may relate to the structure, process, or outcome of health care provided:

Deleted: review
Deleted: an
Deleted: or
Deleted: conducted for
Deleted: purposes

1. The quality of care of one or more health care entities or those services having an impact on care.

Deleted: To maintain or improve the

2. Morbidity or mortality related to one or more health care entities.

Deleted: To reduce m

3. The qualification, competence, conduct, or performance of one or more health care entities.

Deleted: To pursue, enforce, or improve standards of

4. The cost or use of health care services and resources of one or more health care entitites.

provided by?

Deleted: To maintain or advance the appropriate or cost-effective use

5. Pursuing compliance with applicable legal, ethical, or behavioral standards for one or more health care entities.

Pursuit of or just compliance

Deleted: To p
Deleted: e

6. Pursuing compliance with or the performance of credentialing, accreditation, or regulatory activities, requirements, or standards for one ore more health care entities including periodic performance reviews and related activities for the Joint Commission on Accreditation of Healthcare Organizations.

Deleted: To p
Deleted: e
Deleted: ,

7. The approval of the credentialing of one or more health care entities.

8. The health or performance of one or more individuals who are health care entities.

Deleted: To credential, or
Deleted: e
Deleted: ,
Deleted: To address t

- Structure – organizational structure of HCE or other features of HCE relevant to its capacity to provide care
- Process – H. care services provided by HCE
- Outcome – Health state (status) of individ. or individs condition resulting from care provided by HCE

* OR Impact of a h.c. service provided by HCE on individual's Health

9.

Deleted: To measure progress toward or compliance with goals and standards used to further the purposes described in subds. 1. to 8., such as through quality improvement studies, morbidity and mortality studies, or utilization management studies.

TODAY if possible

LRB–1965/P2
RLR:cjs:cs

Wanted by Tues. 1/17 A.M.

PRELIMINARY DRAFT – NOT READY FOR INTRODUCTION

RMR

1 AN ACT *to repeal and recreate* 146.38 of the statutes; **relating to:** health care

2 quality review records.

Analysis by the Legislative Reference Bureau

This is a preliminary draft. An analysis will be provided in a later version.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

3 **SECTION 1.** 146.38 of the statutes is repealed and recreated to read:

4 **146.38 Health care quality review; confidentiality of information.** (1)

5 DEFINITIONS. In this section:

6 (a) "Adverse action" means any action or recommendation to reduce, restrict,

7 suspend, deny, revoke, or fail to renew any of the following:

8 1. A health care entity's clinical privileges or clinical practice authority at a

9 hospital or other health care entity, or a health care entity's membership in a medical

10 staff.

****NOTE: I dropped "professional certification" under subd. 1 because it is covered under subd. 3.

****NOTE: "Medical staff" is not defined in ch. 146. (It is defined and used elsewhere in the statutes to cover health care providers in the corrections system.) Would you like to include the definition of "medical staff" that is provided in HFS 124.02 (10), or should "medical staff" cover medical personnel in other settings besides hospitals?

1 2. A health care entity's participation on a provider panel.

****NOTE: The term "provider panel" is not used in the statutes or the administrative code. Is a provider panel the group of health care providers whose services are covered by a health insurance plan or does it mean something more?

2 4, 3. The accreditation, licensure, or certification of a health care entity. ✓

3 (b) "Evaluation, review, study, or assessment" includes...

****NOTE: I do not think it is necessary, but we could add a clarification stating that an "evaluation, review, study, or assessment" includes any continuous, periodic, or single data collection, study, review, investigation, recommendation, or corrective or other action or process — language from WHA's definition of quality review activity.

4 (b) (c) "Health care entity" means any of the following: INS 2-4

5 1. A health care provider, as defined in s. 146.81 (1), or other person who
6 provides health care services, including mental health services.

7 2. A person who is licensed to arrange for the provision of health care services
8 to an individual.

****NOTE: It is my understanding that subdivision 2. is intended to cover home health agencies. Does it cover anyone else, and, if not, why not specify home health agencies?

9 3. A person who furnishes the services of a person under subd. 1. to another
10 person under subd. 1. or 2.

****NOTE: Do you want to specify that persons providing health care services under a regulated training program (i.e. residents) are health care entities?

****NOTE: It is my understanding that you intend the definition of "health care entity" to include ambulance service providers, emergency medical technicians, and first responders even though this draft does not explicitly include them as under current law ss. 146.37 (1) (a) and 146.38 (1) (b).

INS 2-10

11 (d) "Quality review" means an evaluation, review, study, or assessment
12 conducted for any of the following purposes:

1 1. To maintain or improve the quality of care or those services having an impact
2 on care.
3 2. To reduce morbidity or mortality.
4 3. To pursue, enforce, or improve standards of qualification, competence,
5 conduct, or performance.
6 4. To maintain or advance the appropriate or cost–effective use of health care
7 services and resources.
8 5. To pursue compliance with applicable legal, ethical, or behavioral standards.
9 6. To pursue compliance with credentialing, accreditation, or regulatory
10 activities, requirements, or standards, including periodic performance reviews and
11 related activities for the Joint Commission on Accreditation of Healthcare
12 Organizations.

****NOTE: how does one pursue compliance with an activity?

13 7. To credential, or approve the credentialing of, health care entities.
14 8. To address the health or performance of individuals who are health care
15 entities.

****NOTE: What does it mean for an evaluator/review to "address" the health of an individual in the context of performing a review?

16 9. To measure progress toward or compliance with goals and standards used
17 to further the purposes described in subds. 1. to 8., such as through quality
18 improvement studies, morbidity and mortality studies, or utilization management
19 studies.

****NOTE: What does 9. add that is not covered by 1. to 8.? A study to determine whether an entity is making progress in improving care is a study for the purpose of improving care.

****NOTE: This draft deletes the subjects of review listed in the /P1 and instead uses the purposes language from the WHA draft. I liked the concrete subject areas in /P1 better than purposes because they are less subjective. If you use a list of subjects rather than purposes, then we could make the "structure, process, and outcome of health care"

covered subjects. (Is structure, the structure of the health care entity? Are processes those used by the health care entity to deliver care?)

1 (e) "Records" includes, regardless of the type of communications medium or
2 form, including oral communications, and whether in statistical form or otherwise,
3 minutes, files, notes, reports, statements, memoranda, databases, findings, work
4 products, and images.

****NOTE: This definition of records is from the first part of WHA's definition of "quality review records," except that I removed "proceedings" from the definition, because I don't see how a proceeding can be a record. (Does WHA mean the minutes or record of the proceeding, not the proceeding itself?)

The potential downside of listing items to be included in a definition is that a court might construe the list as all–inclusive regardless of whether the statute says "includes" rather than "means." Therefore I think it is better to limit the list. I used a more limited list in the /P1.

5 (f) "State agency" means a department, board, examining board, affiliated
6 credentialing board, commission, independent agency, council, or office in the
7 executive branch of state government.

****NOTE: This definition is for "state agency" as used in sub. (2) (a) (intro.), to clarify the types of state agencies that may not compel disclosure. It will also apply to sub. (2) (a) 1.

8 **(2)** CONFIDENTIALITY AND PRIVILEGE. (a) Except as provided in sub. (3), all of the
9 following are confidential and privileged; are not subject to discovery, subpoena, or
10 any other means of legal compulsion requiring release or permitting inspection,
11 including compulsion by a state agency; and are not admissible as evidence in any
12 civil, criminal, or other judicial or administrative proceeding:
13 1. Records and information contained in records that are created or collected
14 in preparation for or as part of a quality review that is conducted by the health care
15 entity that is the subject of the review, either alone or with another health care entity,
16 an employee or agent of the health care entity or entities, a fixed or ad hoc committee
17 of the health care entity or entities, or a person to whom the health care entity or
18 entities has granted authority to conduct the quality review, including records of any

1 analysis, conclusions, or recommendations of persons conducting or participating in
2 the quality review.
3 2. Records and information contained in records that are created or collected
4 in preparation for or as part of a quality review that is conducted by a state agency
5 at the request of the health care entity that is the subject of the review.
6 3. Records and information contained in records concerning a health care entity
7 and relating to a quality review purpose under sub. (1) (d) 1. to 9. that are reported
8 to the health care entity or to a person the health care entity has granted authority
9 to conduct quality reviews.
10 4. A request for records or information made as part of a quality review
11 described under subd. 1. or 2. by a person conducting the review.
12 5. Information related to any oversight, monitoring, corrective action, or other
13 action taken in response to a quality review described under subd. 1. or 2.
14 6. The product of aggregating or reorganizing records under subds. 1. to 5. that
15 are voluntarily disclosed by a health care entity for the purpose of aggregation or
16 reorganization.
17 (b) A person who conducts or participates in a quality review described under
18 par. (a) 1. or 2. may not disclose whether the quality review was conducted or disclose
19 action or lack of action taken as a consequence of the quality review.
20 (c) The confidentially and privilege afforded to records and information under
21 par. (a) is not waived by unauthorized or authorized disclosure of records or
22 information. A person who receives records or information under par. (a) 1. to 6. may
23 not further disclose the records or information unless permitted to do so under sub.
24 (3).

1 (d) Records under par. (a) 2. are not subject to inspection or copying under s.
2 19.35 (1).

****NOTE: What if the subject of a review is a government entity, for example a county mental health complex or county nursing home? Should all the confidentiality provisions and the exception to s. 19.35 (1) apply?

3 (3) EXCEPTIONS TO CONFIDENTIALITY AND PRIVILEGE. (a) Subsection (2) does not
4 apply to records or information maintained by or for a health care entity for the
5 particular purpose of diagnosing, treating, or documenting care provided to an
6 individual patient.

7 (b) A person mandated by Wisconsin or federal law to report may disclose a
8 record or information from a record that is confidential and privileged under sub. (2)
9 to make the mandated report.

****NOTE: This exception allows disclosure of the record, not just the information in it — is that ok? The exception allows disclosure, but does not make the disclosed record or information admissible in a court or administrative proceeding. Are there any instances in which an exception to inadmissibility is necessary?

10 (c) If the person who conducts a quality review described under sub. (2) (a) 1.
11 takes an adverse action against a health care entity that is a subject of the review
12 or notifies the health care entity of a proposed adverse action, the person shall, upon
13 request by the health care entity, disclose to the health care entity any records in the
14 person's possession relating to the quality review. The person may at any time
15 disclose to a health care entity records relating to a proposed adverse action by the
16 person against a health care entity. Records relating to the adverse action are
17 admissible in any criminal, civil, or other judicial or administrative proceeding in
18 which the health care entity contests the adverse action.

19 (e) If the health care entity that is the subject of records or information
20 described under sub. (2) (a) provides written authorization for disclosure of the

1 records or information, the records or information may be disclosed to the extent
2 allowed in the written authorization.
3 **(4)** CONSTRUCTION. This section shall be liberally construed in favor of
4 identifying records and information as confidential, privileged, and inadmissible as
5 evidence.

****NOTE: I added inadmissibility here — does it help? Ins 7-5

6 **(END)**

A ***NOTE: Cross-references to this statute will be amended in the next version of this bill to reflect this repeal.

1

2 **Ins 1–3:**

3 SECTION 1. 146.37 of the statutes is repealed.

4

5 **Ins 1–8:**

6 1. A health care entity's clinical privileges or clinical practice authority at a

7 hospital or other health care entity or on a medical staff.

****NOTE: What does it mean for a health care entity to have clinical privileges or clinical practice authority on a medical staff? Does it mean anything different than membership on a medical staff?

8 2. A health care entity's membership on a medical staff or in a hospital or other

9 health care entity.

10 3. A health care entity's participation in a defined network plan, as defined in

11 s. 609.01 (1b).

****NOTE: Subdivision 3. uses the term "defined network plan" instead of "provider panel"?. Please note that the definition "participating" in s. 609.01 (3m) may could be used in construing this bill, which I think is fine.

12

13

14 **Ins 2–4:** (a)

15 1. A health care provider, as defined in s. 146.81 (1), an ambulatory surgery

16 center as defined in s. 153.01 (1), a home health agency, as defined in s. 50.49 (1), a

17 home health aide, as defined in s. 146.40 (1) (bm), a hospice aide, as defined in s.

18 146.40 (1) (bp), a nurse's assistant, as defined in s. 146.40 (1) (d), an ambulance

19 service provider, as defined in s. 146.50 (1) (c), an emergency medical technician, as

including mental health services

1 defined in s. 146.50 (1) (e), a first responder, as defined in s. 146.50 (1) (hm), or any
2 other person who is licensed, certified, or registered to provide health care services.

****NOTE: Dick suggested listing the providers who are missing from 146.81 (1), and leaving out the language regarding "arranging" or "furnishing," because it is vague. I agree with Dick.

3 2. An individual who is enrolled in a education or training program that is
4 approved by an examining board in the department of regulation and licensing or by
5 the department of health and family services and which an individual must complete
6 in order to obtain credentials required of an individual under subd. 1.

that the

7

8 **Ins 2–10:**

9 (c) "Medical staff" means a health care entity's organized component of
10 physicians, podiatrist, or dentists appointed by the governing body of the health care
11 entity and granted specific medical privileges for the purpose of providing adequate
12 medical, podiatric, or dental care for the patients of the health care entity.

****NOTE: This definition is for "medical staff" as used in the definition of "adverse action." It is the same as the definition of "medical staff" in HFS 124.02 (10), except I substituted "health care entity" for "hospital," so it will cover the example of physicians on staff at a clinic. If you define a medical staff to include any group of individuals who provide health care and are employed by a health care entity, for example home health aides, it contorts the meaning of "medical." If you want to cover actions against a nurse or home health aide under the definition of "adverse action," why not include as a subdivision under the definition of adverse action, "employment of an individual as a health care entity?"

13

14 (d) "Quality improvement activity" means an evaluation, review, study,
15 assessment, investigation, recommendation, corrective action, or any other action,
16 including a single, continuous, or periodic data collection relating to any of the
17 following subjects:

one-time

****NOTE: The phrase "structure, process, or outcomes of health care" is used in the health care trade, but doesn't translate well into statutory language without definitions. I looked at the descriptions of structure, process, and outcomes on the National Quality Measures Clearinghouse web site. Process is described as services provided by a health

care entity, which is covered under subd. 1. I added subd. 9. to cover structure and sub. 10. to cover outcomes. Are these additions helpful?

****NOTE: Section 990.001 (1) provides that in the statues the singular includes the plural, and the plural includes the singular, so I just refer to a health care entity rather than one of more health care entities.

1 1. The quality of care provided by a health care entity or the quality of services
2 provided by a health care entity that have an impact on care.
3 2. Morbidity or mortality related to a health care entity.
4 3. The qualification, competence, conduct, or performance of a health care
5 entity.
6 4. The cost or use of health care services and resources of a health care entity.

****NOTE: I am assuming that a health care entity's services are services provided by a health care entity. Is this correct? Subdivision 4. seems to cover 4 subjects: 1) the cost of health care services provided by a health care entity; 2) the use (utilization?) of health care services provided by a health care entity; 3) the cost of a health care entity's resources; and 4) the use of a health care entity's resources. Is this what you intend? The third item is a bit cryptic.

7 5. Compliance with applicable legal, ethical, or behavioral standards for a
8 health care entity.

****NOTE: You don't need to preface the subject as "pursuing compliance" or "pursuit of compliance" because the subject is compliance with standards, which necessarily includes pursuit of compliance.

9 6. Compliance with credentialing, accreditation, or regulatory standards for a
10 health care entity and performance of credentialing, accreditation, or regulatory
11 activities, including compliance with or performance of periodic performance
12 reviews and related activities for the Joint Commission on Accreditation of
13 Healthcare Organizations.
14 7. The approval or credentialing of a health care entity.
15 8. The health of an individual who is a health care entity.

****NOTE: Performance of a health care entity is already covered under subd. 3.

16 9. The organizational structure of a health care entity or other features of a
17 health care entity that are relevant to its capacity to provide care.

1 10. The outcome, with respect to an individual's health or the health of a
2 population, of services provided by a health care entity.

3

4

5 **Ins 4–7:**

6 **(2) Immunity for Acts or Omissions.** (a) Any person acting in good faith who
7 participates in quality improvement activity is not liable for civil damages as a result
8 of any act or omission by the person in the course of the quality improvement activity.
9 Acts or omissions to which this subsection applies include censuring or reprimanding
10 a health care entity, revoking the hospital staff privileges of a health care entity,
11 giving notice to the medical examining board or podiatrist affiliated credentialing
12 board under s. 50.36, or taking any other disciplinary action against a health care
13 entity.

14 (b) The good faith of any person participating in quality improvement activity
15 shall be presumed in any civil action. Any person who asserts that a person has not
16 acted in good faith has the burden of proving that assertion by clear and convincing
17 evidence.

18 (c) In determining whether a person acted in good faith under this subsection,
19 the court shall consider whether the person sought to prevent the health care entity
20 that is the subject of quality improvement activity or its counsel from examining the
21 documents and records used in the quality improvement activity, from presenting
22 witnesses, establishing pertinent facts or circumstances, questioning or refuting
23 testimony or evidence, or confronting or cross–examining adverse witnesses, or from
24 receiving a copy of the final report or recommendation resulting from quality
25 improvement activity.

1
2
3 **Ins 4–12:**

4 1. Records and information contained in records that are created or collected
5 by or presented to a person who requests or conducts any of the following types of
6 quality improvement activities in preparation for or as part of the quality
7 improvement activity:

****NOTE: I changed this subdivision to specify who creates or collects the records and also added presented records, which were covered under sub. (2) (a) 3. in the /P2 draft. Please review whether the specification of who creates or collects records or who receives presented records is accurate.

8 a. A quality improvement activity concerning a health care entity that is
9 conducted by or at the request of a person who employs or contracts with the health
10 care entity.

****NOTE: I added this subdivision paragraph to cover several scenarios we discussed: 1) a review by a hospital of a doctor and 2) a review by an entity that owns several hospitals of one or more of the hospitals.

11 b. A quality improvement activity that is conducted by the health care entity
12 that is the subject of the activity, either alone or with another health care entity.

13 c. A quality improvement activity that is conducted by an employee or a fixed
14 or ad hoc committee of the health care entity or entities that are the subject of the
15 quality improvement activity.

****NOTE: The definition in Webster's for "ad hoc" is: a) 1. concerned with a particular end or purpose, 2. formed or used for specific or immediate problems or needs b) fashioned from whatever is immediately available. I think this definition fits your intent.

****NOTE: I removed agent, because activities by agents are covered under subdivision paragraph d.

16 d. A quality improvement activity that is conducted by a person to whom the
17 health care entity or entities that are the subject of the activity have granted
18 authority to conduct the activity.

e. A quality improvement activity conducted by a state agency at the request of the health care entity or entities that are the subject of the activity.

****NOTE: This subdivision paragraph is sub. (2) (a) 2. from the /P2 draft.

Ins 5–11:

3. Notice to a health care entity that he or she is or will be the subject of a quality improvement activity described under subd. 1.

Ins 6–2:

****NOTE: I changed the provision concerning public records so that records relating to a review conducted by DHFS at the request of a public health care entity are not exempted from inspection under the public records law. However, the bill still makes confidential records of any quality improvement activity related to a public health care entity that is conducted by the health care entity or by a private entity. This may set up a conflict with the public records law.

Ins 6–10:

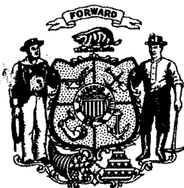
If a person takes an adverse action against a health care entity as part of a quality improvement activity described under sub. (2) (a) 1.,

Ins 6–19:

If the person who conducts or requests quality improvement activity described under sub. (2) (a) 1. a., or the health care entity that is the subject of quality improvement activity described under sub. (2) (a) 1. b. to e., provides written authorization for disclosure of records and information related to the quality improvement activity,

1 **Ins 7–5:**

We discussed removing reference in the bill to "privilege," since a privilege is generally a right of a person that extends to communications or work product and the bill does not establish who holds the privilege. Also privileges are generally established under ch. 905. However, some of the court cases on peer review records do refer to "privileged material." I am still in favor of removing the term, because the language on confidentiality, protection against discovery, and on inadmissibility accomplishes your intent.



State of Wisconsin
2005 – 2006 LEGISLATURE

LRB–1965/P3
RLR:cjs:jf

PRELIMINARY DRAFT – NOT READY FOR INTRODUCTION

1 AN ACT *to repeal* 146.37; and *to repeal and recreate* 146.38 of the statutes;
2 **relating to:** confidentiality of health care review records and immunity.

Analysis by the Legislative Reference Bureau

This is a preliminary draft. An analysis will be provided in a later version.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

3 SECTION 1. 146.37 of the statutes is repealed.

****NOTE: Cross–references to this statute will be amended in the next version of this bill to reflect this repeal.

4 SECTION 2. 146.38 of the statutes is repealed and recreated to read:

5 **146.38 Health care quality improvement activity. (1)** DEFINITIONS. In this
6 section:

7 (a) "Adverse action" means any action or recommendation to reduce, restrict,
8 suspend, deny, revoke, or fail to renew any of the following:

9 1. A health care entity's clinical privileges or clinical practice authority at a
10 hospital or other health care entity or on a medical staff.

****NOTE: What does it mean for a health care entity to have clinical privileges or clinical practice authority on a medical staff? Does it mean anything different than membership on a medical staff?

1 2. A health care entity's membership on a medical staff or in a hospital or other
2 health care entity.
3 3. A health care entity's participation in a defined network plan, as defined in
4 s. 609.01 (1b).

****NOTE: Subdivision 3. uses the term "defined network plan" instead of "provider panel." Please note that the definition "participating" in s. 609.01 (3m) could be used in construing this bill, which I think is fine.

5 4. The accreditation, licensure, or certification of a health care entity.
6 (b) "Health care entity" means any of the following:
7 1. A health care provider, as defined in s. 146.81 (1), an ambulatory surgery
8 center as defined in s. 153.01 (1), a home health agency, as defined in s. 50.49 (1) (a),
9 a home health aide, as defined in s. 146.40 (1) (bm), a hospice aide, as defined in s.
10 146.40 (1) (bp), a nurse's assistant, as defined in s. 146.40 (1) (d), an ambulance
11 service provider, as defined in s. 146.50 (1) (c), an emergency medical technician, as
12 defined in s. 146.50 (1) (e), a first responder, as defined in s. 146.50 (1) (hm), or any
13 other person who is licensed, certified, or registered to provide health care services
14 including mental health services.

****NOTE: Dick suggested listing the providers who are missing from 146.81 (1), and leaving out the language regarding "arranging" or "furnishing," because it is vague. I agree with Dick.

15 2. An individual who is enrolled in a education or training program that is
16 approved by an examining board in the department of regulation and licensing or by
17 the department of health and family services and that the individual must complete
18 in order to obtain credentials required of an individual under subd. 1.
19 (c) "Medical staff" means a health care entity's organized component of
20 physicians, podiatrists, or dentists appointed by the governing body of the health

1 care entity and granted specific medical privileges for the purpose of providing
2 adequate medical, podiatric, or dental care for the patients of the health care entity.

****NOTE: This definition is for "medical staff" as used in the definition of "adverse action." It is the same as the definition of "medical staff" in HFS 124.02 (10), except I substituted "health care entity" for "hospital," so it will cover the example of physicians on staff at a clinic. If you define a medical staff to include any group of individuals who provide health care and are employed by a health care entity, for example home health aides, it contorts the meaning of "medical." If you want to cover actions against a nurse or home health aide under the definition of "adverse action," why not include as a subdivision under the definition of adverse action, "employment of an individual as a health care entity?"

3 (d) "Quality improvement activity" means an evaluation, review, study,
4 assessment, investigation, recommendation, corrective action, or any other action,
5 including one–time, continuous, or periodic data collection relating to any of the
6 following subjects:

****NOTE: The phrase "structure, process, or outcomes of health care" is used in the health care trade, but doesn't translate well into statutory language without definitions. I looked at the descriptions of structure, process, and outcomes on the National Quality Measures Clearinghouse Web site. Process is described as services provided by a health care entity, which is covered under subd. 1. I added subd. 9. to cover structure and subd. 10. to cover outcomes. Are these additions helpful?

****NOTE: Section 990.001 (1) provides that in the statues the singular includes the plural, and the plural includes the singular, so I just refer to a health care entity rather than one or more health care entities.

7 1. The quality of care provided by a health care entity or the quality of services
8 provided by a health care entity that have an impact on care.
9 2. Morbidity or mortality related to a health care entity.
10 3. The qualification, competence, conduct, or performance of a health care
11 entity.
12 4. The cost or use of health care services and resources of a health care entity.

****NOTE: I am assuming that a health care entity's services are services provided by a health care entity. Is this correct? Subdivision 4. seems to cover 4 subjects: 1) the cost of health care services provided by a health care entity; 2) the use (utilization?) of health care services provided by a health care entity; 3) the cost of a health care entity's resources; and 4) the use of a health care entity's resources. Is this what you intend? The third item is a bit cryptic.

1 5. Compliance with applicable legal, ethical, or behavioral standards for a
2 health care entity.

****NOTE: You don't need to preface the subject as "pursuing compliance" or "pursuit of compliance" because the subject is compliance with standards, which necessarily includes pursuit of compliance.

3 6. Compliance with credentialing, accreditation, or regulatory standards for a
4 health care entity and performance of credentialing, accreditation, or regulatory
5 activities, including compliance with or performance of periodic performance
6 reviews and related activities for the Joint Commission on Accreditation of
7 Healthcare Organizations.
8 7. The approval or credentialing of a health care entity.
9 8. The health of an individual who is a health care entity.

****NOTE: Performance of a health care entity is already covered under subd. 3.

10 9. The organizational structure of a health care entity or other features of a
11 health care entity that are relevant to its capacity to provide care.
12 10. The outcome, with respect to an individual's health or the health of a
13 population, of services provided by a health care entity.
14 (e) "Records" includes, regardless of the type of communications medium or
15 form, including oral communications, and whether in statistical form or otherwise,
16 minutes, files, notes, reports, statements, memoranda, databases, findings, work
17 products, and images.

****NOTE: This definition of records is from the first part of WHA's definition of "quality review records," except that I removed "proceedings" from the definition, because I don't see how a proceeding can be a record. (Does WHA mean the minutes or record of the proceeding, not the proceeding itself?)

The potential downside of listing items to be included in a definition is that a court might construe the list as all–inclusive regardless of whether the statute says "includes" rather than "means." Therefore I think it is better to limit the list. I used a more limited list in the /P1.

1 (f) "State agency" means a department, board, examining board, affiliated
2 credentialing board, commission, independent agency, council, or office in the
3 executive branch of state government.

****NOTE: This definition is for "state agency" as used in sub. (3) (a) (intro.), to clarify the types of state agencies that may not compel disclosure. It will also apply to sub. (3) (a) 1. e.

4 **(2)** IMMUNITY FOR ACTS OR OMISSIONS. (a) No person acting in good faith who
5 participates in a quality improvement activity is liable for civil damages as a result
6 of any act or omission by the person in the course of the quality improvement activity.
7 Acts or omissions to which this subsection applies include censuring or reprimanding
8 a health care entity, revoking the hospital staff privileges of a health care entity,
9 giving notice to the medical examining board or podiatrist affiliated credentialing
10 board under s. 50.36, or taking any other disciplinary action against a health care
11 entity.

12 (b) The good faith of any person participating in a quality improvement activity
13 shall be presumed in any civil action. Any person who asserts that a person has not
14 acted in good faith has the burden of proving that assertion by clear and convincing
15 evidence.

16 (c) In determining whether a person acted in good faith under this subsection,
17 the court shall consider whether the person sought to prevent the health care entity
18 that is the subject of the quality improvement activity or its counsel from examining
19 the documents and records used in the quality improvement activity, from
20 presenting witnesses, establishing pertinent facts or circumstances, questioning or
21 refuting testimony or evidence, or confronting or cross–examining adverse witnesses
22 or from receiving a copy of the final report or recommendation resulting from the
23 quality improvement activity.

1 (3) CONFIDENTIALITY AND PRIVILEGE. (a) Except as provided in sub. (4), all of the
2 following are confidential and privileged; are not subject to discovery, subpoena, or
3 any other means of legal compulsion requiring release or permitting inspection,
4 including compulsion by a state agency; and are not admissible as evidence in any
5 civil, criminal, or other judicial or administrative proceeding:

6 1. Records and information contained in records that are created or collected
7 by or presented to a person who requests or conducts any of the following types of
8 quality improvement activities in preparation for or as part of the quality
9 improvement activity:

****NOTE: I changed this subdivision to specify who creates or collects the records and also added presented records, which were covered under sub. (2) (a) 3. in the /P2 draft. Please review whether the specification of who creates or collects records or who receives presented records is accurate.

10 a. A quality improvement activity concerning a health care entity that is
11 conducted by or at the request of a person who employs or contracts with the health
12 care entity.

****NOTE: I added this subdivision paragraph to cover several scenarios we discussed: 1) a review by a hospital of a doctor; and 2) a review by an entity that owns several hospitals of one or more of the hospitals.

13 b. A quality improvement activity that is conducted by the health care entity
14 that is the subject of the activity, either alone or with another health care entity.

15 c. A quality improvement activity that is conducted by an employee or a fixed
16 or ad hoc committee of the health care entity or entities that are the subject of the
17 quality improvement activity.

****NOTE: The definition in Webster's for "ad hoc" is: a) 1. concerned with a particular end or purpose, 2. formed or used for specific or immediate problems or needs; b) fashioned from whatever is immediately available. I think this definition fits your intent.

****NOTE: I removed agent, because activities by agents are covered under subdivision paragraph d.

1 d. A quality improvement activity that is conducted by a person to whom the
2 health care entity or entities that are the subject of the activity have granted
3 authority to conduct the activity.

4 e. A quality improvement activity conducted by a state agency at the request
5 of the health care entity or entities that are the subject of the activity.

****NOTE: This subdivision paragraph is sub. (2) (a) 2. from the /P2 draft.

6 2. A request for records or information made as part of a quality improvement
7 activity described under subd. 1. by a person conducting the quality improvement
8 activity.

9 3. Notice to a health care entity that he or she is or will be the subject of a quality
10 improvement activity described under subd. 1.

11 4. The product of aggregating or reorganizing records or information under
12 subds. 1. to 3. that are voluntarily disclosed by a health care entity for the purpose
13 of aggregation or reorganization.

14 (b) A person who conducts or participates in a quality improvement activity
15 described under par. (a) 1. may not disclose whether the quality improvement
16 activity was conducted or disclose action or lack of action taken as a consequence of
17 the quality improvement activity.

18 (c) The confidentially and privilege afforded to records and information under
19 par. (a) is not waived by unauthorized or authorized disclosure of records or
20 information. A person who receives records or information under par. (a) 1. to 4. may
21 not further disclose the records or information unless permitted to do so under sub.
22 (4).

1 (d) Records relating to a quality improvement activity described under par. (a)
2 1. e. are not subject to inspection or copying under s. 19.35 (1) if the subject of the
3 quality improvement activity is not a government entity.

****NOTE: I changed the provision concerning public records so that records relating to a review conducted by DHFS at the request of a public health care entity are not exempted from inspection under the public records law. However, the bill still makes confidential records of any quality improvement activity related to a public health care entity that is conducted by the health care entity or by a private entity. This may set up a conflict with the public records law.

4 **(4)** EXCEPTIONS TO CONFIDENTIALITY AND PRIVILEGE. (a) Subsection (3) does not
5 apply to records or information maintained by or for a health care entity for the
6 particular purpose of diagnosing, treating, or documenting care provided to an
7 individual patient.

8 (b) A person mandated by Wisconsin or federal law to report may disclose a
9 record or information from a record that is confidential and privileged under sub. (3)
10 to make the mandated report.

11 (c) If a person takes an adverse action against a health care entity as part of
12 a quality improvement activity described under sub. (3) (a) 1., or notifies the health
13 care entity of a proposed adverse action, the person shall, upon request by the health
14 care entity, disclose to the health care entity any records in the person's possession
15 relating to the quality improvement activity that are relevant to the adverse action.
16 The person may at any time disclose to the health care entity records relating to the
17 quality improvement activity that is relevant to the proposed adverse action by the
18 person against the health care entity. Records relating to the quality improvement
19 activity that are relevant to the adverse action are admissible in any criminal, civil,
20 or other judicial or administrative proceeding in which the health care entity
21 contests the adverse action.

1 (d) If the person who conducts or requests a quality improvement activity
2 described under sub. (3) (a) 1. a., or the health care entity that is the subject of a
3 quality improvement activity described under sub. (3) (a) 1. b. to e., provides written
4 authorization for disclosure of records and information related to the quality
5 improvement activity, the records or information may be disclosed to the extent
6 allowed in the written authorization.

7 **(4)** CONSTRUCTION. This section shall be liberally construed in favor of
8 identifying records and information as confidential, privileged, and inadmissible as
9 evidence.

****NOTE: I added inadmissibility here — does it help? We discussed removing reference in the bill to "privilege," since a privilege is generally a right of a person that extends to communications or work product and the bill does not establish who holds the privilege. Also privileges are generally established under ch. 905. However, some of the court cases on peer review records do refer to "privileged material." I am still in favor of removing the term, because the language on confidentiality, protection against discovery, and on inadmissibility accomplishes your intent.

10 **(END)**