2005 DRAFTING REQUEST

Assembly Substitute Amendment (ASA-AB993)

Received: **02/13/2006**

Received By: **dkennedy**

Wanted: **As time permits**

Identical to LRB:

For: **Gregg Underheim (608) 266-2254**

By/Representing: **Randy (aide)**

This file may be shown to any legislator: **NO**

Drafter: **dkennedy**

May Contact:

Addl. Drafters: **rryan**

Subject: **Health - miscellaneous**

Extra Copies:

Submit via email: **YES**

Requester's email: **Rep.Underheim@legis.state.wi.us**

Carbon copy (CC:) to: **richard.sweet@legis.state.wi.us**
laura.rose@legis.state.wi.us

Pre Topic:

No specific pre topic given

Topic:

Confidentiality of records and information related to quality improvement activity

---

Instructions:

See Attached

Drafting History:

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
/?	dkennedy 02/13/2006	csicilia 02/13/2006		_____ _____			
/1			pgreensl 02/13/2006	_____ _____	mbarman 02/13/2006	mbarman 02/13/2006	
/2	dkennedy 02/14/2006	csicilia 02/14/2006	pgreensl 02/14/2006	_____ _____	lnorthro 02/14/2006	lnorthro 02/14/2006	

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
/3	dkennedy 02/15/2006	csicilia 02/15/2006	pgreensl 02/15/2006	_____ _____	sbasford 02/15/2006	sbasford 02/15/2006	
/4	dkennedy 02/15/2006	csicilia 02/15/2006	rschluet 02/16/2006	_____ _____	mbarman 02/16/2006	mbarman 02/16/2006	

FE Sent For:

<END>

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/2	dkennedy 02/14/2006	csicilia 02/14/2006	pgreensl 02/14/2006	_____ _____	lnorthro 02/14/2006	lnorthro 02/14/2006	

2168

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
/3	dkennedy 02/15/2006	csicilia 02/15/2006	pgreensl 02/15/2006	_____ _____	sbasford 02/15/2006	sbasford 02/15/2006	

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<END>

/4 gs 2/15/06

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/2	dkennedy 02/14/2006	csicilia 02/14/2006	pgreensl 02/14/2006	_____ _____	lnorthro 02/14/2006	lnorthro 02/14/2006	

/3 jfs 2/15/05 9:58 RSM

FE Sent For:

<END>

REVISION REPORT

INTRODUCTION, FIRST READING AND REFERENCE OF PROPOSALS

Under Assembly Rule 17d,

Tuesday, February 14, 2006 at 10:18 AM

is considered the official date and time of introduction for the proposals listed in this document.

****

ASSEMBLY JOINT RESOLUTION 78 (LRB –4652)

Relating to: the life and public serve of Coretta Scott King.

By Representatives Young, A. Williams, Grigsby, Fields, Toles, Turner, Hebl, Sherman and Richards.

Referred to Committee on **RULES**.

2005 DRAFTING REQUEST

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Pre Topic:

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Instructions:

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/?	dkennedy 02/13/2006	csicilia 02/13/2006					
/1		/2 gs 2/14 06	pgreensl 02/13/2006	2/14 2/14 PS/K PS	mbarman 02/13/2006	mbarman 02/13/2006	

FE Sent For:

<END>

2005 DRAFTING REQUEST

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Wanted: **As time permits**

Identical to LRB:

For: **Gregg Underheim (608) 266-2254**

By/Representing: **Randy (aide)**

This file may be shown to any legislator: **NO**

Drafter: **dkennedy**

May Contact:

Addl. Drafters: **rryan**

Subject: **Health - miscellaneous**

Extra Copies: **Dick Sweet, Laura Rose (Leg. Council)**

Submit via email: **YES**

Requester's email: **Rep.Underheim@legis.state.wi.us**

Carbon copy (CC:) to:

Pre Topic:

No specific pre topic given

Topic:

Confidentiality of records and information related to quality improvement activity

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Instructions:

See Attached

Drafting History:

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
/?	dkennedy	/1 gjs 2/13 OC	2/13 p8	2/13 p8 lle			

FE Sent For:

<END>

Jim Doyle
Governor

Celia M. Jackson
Secretary

WISCONSIN DEPARTMENT OF REGULATION & LICENSING

1400 E Washington Ave
PO Box 8935
Madison WI 53708-8935
Email: web@drl.state.wi.us
Voice: 608-266-2112
FAX: 608-267-0644
TTY: 608-267-2416

Assembly Committee on Health
Senate Committee on Health, Children, Families, Aging and Long Term Care

Testimony of Eric Callisto

February 8, 2006

AB 993/SB 578 - Bills Relating to Confidentiality of Health Care Review Records and Immunity

Committee Members:

Thank you for giving me the opportunity to testify today. My name is Eric Callisto, and I am the Administrator of the Division of Enforcement at the Department of Regulation and Licensing. I am testifying for informational purposes only, and I bring to the Committees' attention a number of points related to the Department's review of the most recent available draft of AB 993, which I have attached.

The Department has no objection to peer review, in concept or in practice. There is undoubtedly benefit to the medical community and the public from the availability of a forum for open discussion of the difficult issues faced daily by our treatment providers. The following comments are focused on ensuring that the bill does not unnecessarily weaken the Department's ability to enforce where needed, and to notify the public of such activities where appropriate. The Department would welcome the opportunity to further discuss these suggestions with members of the Committees and drafting staff.

Page 4, line 5: The phrase "adverse action" is drafted to include enforcement actions such as those conducted by the Division. It should be expanded to include the disciplinary options of limitation and reprimand, and it should include investigative activities. The same suggestion applies to page 8, line 11.

Page 6, lines 15-18: As described below, the inclusion of "oral communications" in the definition of "records" is very broad, and may pose difficulties for Division investigators and prosecutors attempting to use such statements in prosecutions.

Page 7, lines 10-14: The category of records and information protected by the new language is extremely inclusive. Valuable information will be lost to the Division by the aggressive "collection" or "aggregation" of relevant records. For example, a physician's hallway admission of wrongdoing to a staff member could be pulled into the protected category if the individual conducting the quality improvement activity was made aware of the conversation.

Page 7, lines 15-17: It appears that the quality improvement activities of the Department are not subject to the confidentiality and privilege provisions. Our enforcement activities, and

documents created therein, can be accessed, and their production compelled, by outside parties. This is consistent with current law. The strength of this exception is unclear as a result of language used in the following sections:

- Page 8, lines 4-5: Records "described under par. (a)1. are not subject to inspection or copying under 19.35(1)." While the Department's activities are exempt from the confidentiality and privilege provisions, they are arguably still "described" in paragraph (a)1. Thus a reasonable reading of this provision, particularly given the proposed statutory construction clause which mandates construing the language in favor of confidentiality, is that Department enforcement records are not subject to the open records law. This would be a dramatic change from current practice. An alternative draft could read "Records relating to a quality improvement activity that are confidential and privileged under par. (a) 1. are not subject to inspection or copying under s. 19.35 (1)."

- Page 8, line 17 through page 9, line 2: If the Department's activities are exempt from the confidentiality and privilege provisions, then paragraph (4)(d) does not apply at all. Because the text uses the phrase "described under sub. (3)(a)1.", the same potential issue arises as above, as the Department's activities are arguably "described" in the subject paragraph. Additionally, Department investigations that could be viewed as "proposed adverse action[s]." Because there is no (3)(a)1.a. limitation in that phrase, all of the Division's enforcement activities could fall under the limitations of (4)(d). The alternative drafting noted above would resolve this issue.

  If paragraph (4)(d) applies to Department activities then the disclosure requirements listed therein go beyond what is otherwise required by the rules of discovery applicable to our proceedings. This paragraph also gives substantial discretion to respondents in Department enforcement actions in regard to how the Department's records can be used against them. Neither of these results is mandated by current law, or is desirable.

a. A person, other than a state agency, who is required or authorized by state or federal law, as a condition of accreditation, or under a bylaw, resolution, or policy to conduct the quality improvement activity, or another person who acts on that person's behalf.

b. A person who is charged, authorized, or directed by a person described in subd. 1. a. to conduct the quality improvement activity.

2. Subdivision (3)(a)1. includes ~~A~~ a request for records or information made as part of a quality improvement activity described under subd. 1. by a person conducting the quality improvement activity.

3. Subdivision (3)(a)1. includes a ~~N~~notice to a health care entity that the entity is or will be the subject of a quality improvement activity confidential and privileged~~described~~ under subd. 1.

(b) Except as provided in sub. (4) (c) and(g), the confidentiality and privilege afforded to records and information under par. (a) is not waived by unauthorized or authorized disclosure of records or information.

(c) Records relating to a quality improvement activity ~~described~~ that are confidential and privileged under par. (a) 1. are not subject to inspection or copying under s. 19.35 (1).

(4) EXCEPTIONS TO CONFIDENTIALITY AND PRIVILEGE. (a) Subsection (3) does not apply to records or information created or obtained apart from a quality improvement activity when they are in the hands of a person not conducting quality improvement activity or who was not conducting quality improvement activity when obtained or created, nor does subsection (3) apply to records or information created or obtained apart from a quality improvement activity that are maintained by or for a health care entity for the particular purpose of diagnosing, treating, or documenting care provided to an individual patient.

(aa) Any person who testifies during or participates in a quality improvement activity confidential and privileged under sub. (3)(a)1. may testify in any civil, criminal, or other judicial or administrative proceeding as to matters within his or her knowledge, but may not testify as to information obtained through his or her participation in a quality improvement activity confidential and privileged under sub. (3)(a)1., nor as to any conclusion of such quality improvement activity.

(b) Subsection (3) does not prohibit disclosing that a reduction, restriction, suspension, denial, revocation, or failure to renew any item under sub. (1) (a) 1. to 4. has occurred.

a. A person, other than a state agency, who is required or authorized by state or federal law, as a condition of accreditation, or under a bylaw, resolution, or policy to conduct the quality improvement activity, or another person who acts on that person's behalf.

b. A person who is charged, authorized, or directed by a person described in subd. 1. a. to conduct the quality improvement activity.

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(b) Except as provided in sub. (4) (c) and(g), the confidentiality and privilege afforded to records and information under par. (a) is not waived by unauthorized or authorized disclosure of records or information.

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Jim Doyle
Governor

Celia M. Jackson
Secretary

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TTY: 608-267-2416

DRL Comments on AB 993/SB 578

February 10, 2006

These comments supplant those provided in the Department's written testimony of February 8, 2006, and are based upon the understanding that the legislation is not intended to preclude DRL's enforcement activities from the expanded reach of the new language. The comments are specific to Assembly Substitute Amendment 1 to AB 993 and its companion amendment in the Senate.

- Page 5, lines 6-9: As currently written, the treatment language at the back end of the paragraph qualifies the entire paragraph. Thus, only treatment records that are created "apart from" the QIA are excepted. Read in tandem with (3)(a)1., I believe this construction allows a peer review committee to pull into the protected category nontreatment records that are created outside of the QIA process. The example I used with WHA counsel yesterday is that of a private letter written by a physician to a friend in which the physician admits to wrongdoing. If "collected" by the QIA, I do not believe that document would then be available to DRL prosecutors. Other records impacted by this interpretation are letters from physicians to insurance companies, and incident reports at the hospital unrelated to peer review. If the intent of the language is to exempt records and information that are created outside of the QIA process, I believe the following amendment to (4)(a) would achieve this:

  > Subsection (3) does not apply to records or information created apart from a quality improvement activity or that are maintained by or for a health care entity for the particular purpose of diagnosing, treating, or documenting care provided to an individual patient.

- Page 5, lines 17-21: I think the language needs to make clear that the "proposed adverse action" is also subject to the limitation that such must first be "described under sub (3)(a)1." This is implicit in that this language is found in the exceptions paragraph, but its current structure could raise the possibility that paragraph (4)(d) applies to all "proposed adverse action," not just that which is described under (3)(a)1. This would include Department activity. Suggested language:

  > If a person takes an adverse action against a health care entity as part of a quality improvement activity described under sub. (3)(a)1., or notifies the health care entity of a proposed adverse action described under sub. (3)(a)1., the person shall . . . ."

- General: The phrase "described under" is used throughout the bill. In (4)(c) and (f) the phrase "pursuant to" is used (page 6, lines 3 and 6). It isn't clear if that is an intentional difference, and if so, what does it mean? Also, for consistency, the initial language in (4)(h) should be "A person planning an activity that would be a quality improvement activity described under sub. (3)(a)1. . . . ." (page 6, lines 14-15).

Eric Callisto
DRL

''PART C—PATIENT SAFETY IMPROVEMENT

''SEC. 921. DEFINITIONS.

''In this part:

''(1) HIPAA CONFIDENTIALITY REGULATIONS.—The term 'HIPAA confidentiality regulations' means regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033).

''(2) IDENTIFIABLE PATIENT SAFETY WORK PRODUCT.—The term 'identifiable patient safety work product' means patient safety work product that—

''(A) is presented in a form and manner that allows the identification of any provider that is a subject of the work product, or any providers that participate in activities that are a subject of the work product;

''(B) constitutes individually identifiable health information as that term is defined in the HIPAA confidentiality regulations; or

''(C) is presented in a form and manner that allows the identification of an individual who reported information in the manner specified in section 922(e).

''(3) NONIDENTIFIABLE PATIENT SAFETY WORK PRODUCT.—The term 'nonidentifiable patient safety work product' means patient safety work product that is not identifiable patient safety work product (as defined in paragraph (2)).

''(4) PATIENT SAFETY ORGANIZATION.—The term 'patient safety organization' means a private or public entity or component thereof that is listed by the Secretary pursuant to section 924(d).

''(5) PATIENT SAFETY ACTIVITIES.—The term 'patient safety activities' means the following activities:

''(A) Efforts to improve patient safety and the quality of health care delivery.

''(B) The collection and analysis of patient safety work product.

''(C) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.

''(D) The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk.

''(E) The maintenance of procedures to preserve confidentiality with respect to patient safety work product.

''(F) The provision of appropriate security measures with respect to patient safety work product.

''(G) The utilization of qualified staff.

''(H) Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

''(6) PATIENT SAFETY EVALUATION SYSTEM.—The term 'patient safety evaluation system' means the collection, management, or analysis of information for reporting to or by a patient safety organization.

''(7) PATIENT SAFETY WORK PRODUCT.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), the term 'patient safety work product' means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements—

''(i) which—

''(I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or

''(II) are developed by a patient safety organization for the conduct of patient safety activities; and which could result in improved patient safety, health care quality, or health care outcomes; or

''(ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

''(B) CLARIFICATION.—

''(i) Information described in subparagraph (A) does not include a patient's medical record, billing and discharge information, or any other original patient or provider record.

''(ii) Information described in subparagraph (A) does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product.

''(iii) Nothing in this part shall be construed to limit—

''(I) the discovery of or admissibility of information described in this subparagraph in a criminal, civil, or administrative proceeding;

''(II) the reporting of information described in this subparagraph to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes; or

''(III) a provider's recordkeeping obligation with respect to information described in this subparagraph under Federal, State, or local law.

''(8) PROVIDER.—The term 'provider' means—

''(A) an individual or entity licensed or otherwise authorized under State law to provide health care services, including—

''(i) a hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office, long term care facility, behavior health residential treatment facility, clinical laboratory, or health center; or

''(ii) a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner; or

''(B) any other individual or entity specified in regulations promulgated by the Secretary.

''SEC. 922. PRIVILEGE AND CONFIDENTIALITY PROTECTIONS.

''(a) PRIVILEGE.—Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c), patient safety work product shall be privileged and shall not be—

''(1) subject to a Federal, State, or local civil, criminal, or administrative subpoena or order, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;

2/10/06 Laura Leitch, Matt Stanford (WHA), Dick Sweet

1. ~~described under~~ use "under" p. 6

2. delete ("~~under sub (2) (a) 1.~~ + sub.") to which sub (3) applies"

3. p. 3, ll 21 + 25
Eric to call DOJ + e-mail – supplants st. emp immunity
make inapplic. to st employee immunity

4. R+L Doesn't want abil. to get independently-created evid trumped by this stat.

5. Matt:
Big able to receive testimony from friend –
OR Exception in (4):
Any person who testifies due on participation in a gia under (3) may testify in any [illegible] – See attached w/ changes (A)

6. Work product – pd definition

Kennedy, Debora

From: Callisto, Eric - DRL [Eric.Callisto@drl.state.wi.us]
Sent: Friday, February 10, 2006 4:08 PM
To: 'Leitch, Laura'; Sweet, Richard; Topinka, Ralph; Kennedy, Debora; Stanford, Matthew
Cc: Berndt, Michael; Gloe, Steve; Schuh, Dennis - DRL
Subject: RE: Quality Improvement Act

Thanks for the meeting today, and the progress we made. We can be available any time on Monday morning, though my preference is 11:00. As mentioned, we'll assume this is in the same room at LRB.

If you can get us a draft to look at on the specific remaining section, that would be helpful. I'll also work on some suggested language. Thanks.

-----Original Message-----
From: Leitch, Laura [mailto:LLeitch@wha.org]
Sent: Friday, February 10, 2006 11:20 AM
To: eric.callisto@drl.state.wi.us; 'Richard. Sweet (E-mail); Topinka, Ralph; Debora Kennedy (E-mail); Stanford, Matthew
Cc: Borgerding, Eric; Jennifer Stegall (E-mail); 'Randy. Thorson (E-mail)
Subject: RE: Quality Improvement Act

Attached are the comments from DRL that we'll discuss at the meeting this afternoon.

Thanks!

<<DRLcomments.pdf>>

> -----Original Message-----
> From: Leitch, Laura
> Sent: Thursday, February 09, 2006 2:25 PM
> To: 'eric.callisto@drl.state.wi.us'; 'Richard. Sweet (E-mail); Topinka, Ralph; Debora Kennedy (E-mail); Stanford, Matthew
> Cc: Borgerding, Eric; Jennifer Stegall (E-mail); 'Randy. Thorson (E-mail)
> Subject: Quality Improvement Act
>
> The meeting to resolve the Department of Regulation and Licensing's
> concerns with the QIA is scheduled for tomorrow, Friday, at 1:30 pm.
> Dick Sweet has graciously agreed to host the event in Legislative
> Council conference room at 1 East Main.
>
> Eric, if you have anything in writing before the meeting, it would be
> great if you could shoot it to the group.
>
> Thanks everyone and see you tomorrow.
>
> Laura

a. A person, other than a state agency, who is required or authorized by state or federal law, as a condition of accreditation, or under a bylaw, resolution, or policy to conduct the quality improvement activity, or another person who acts on that person's behalf.

b. A person who is charged, authorized, or directed by a person described in subd. 1. a. to conduct the quality improvement activity.

2. Subdivision (3)(a)1. includes ~~A~~ a request for records or information made as part of a quality improvement activity described under subd. 1. by a person conducting the quality improvement activity.

3. Subdivision (3)(a)1. includes a ~~N~~notice to a health care entity that the entity is or will be the subject of a quality improvement activity confidential and privileged~~described~~ under subd. 1.

(b) Except as provided in sub. (4) (c) and(g), the confidentiality and privilege afforded to records and information under par. (a) is not waived by unauthorized or authorized disclosure of records or information.

(c) Records relating to a quality improvement activity ~~described~~ that are confidential and privileged under par. (a) 1. are not subject to inspection or copying under s. 19.35 (1).

(4) EXCEPTIONS TO CONFIDENTIALITY AND PRIVILEGE. (a) Subsection (3) does not apply to records or information created or obtained apart from a quality improvement activity when they are in the hands of a person not conducting quality improvement activity or who was not conducting quality improvement activity when obtained or created, nor does subsection (3) apply to records or information created or obtained apart from a quality improvement activity that are maintained by or for a health care entity for the particular purpose of diagnosing, treating, or documenting care provided to an individual patient.

(aa) Any person who testifies during or participates in a quality improvement activity confidential and privileged under sub. (3)(a)1. may testify in any civil, criminal, or other judicial or administrative proceeding as to matters within his or her knowledge, but may not testify as to information obtained through his or her participation in a quality improvement activity confidential and privileged under sub. (3)(a)1., nor as to any conclusion of such quality improvement activity.

(b) Subsection (3) does not prohibit disclosing that a reduction, restriction, suspension, denial, revocation, or failure to renew any item under sub. (1) (a) 1. to 4. has occurred.

Kennedy, Debora

From: Callisto, Eric - DRL [Eric.Callisto@drl.state.wi.us]
Sent: Monday, February 13, 2006 9:38 AM
To: Callisto, Eric - DRL; Sweet, Richard; Leitch, Laura; Topinka, Ralph; Kennedy, Debora; Stanford, Matthew
Cc: Berndt, Michael; Gloe, Steve; Schuh, Dennis - DRL
Subject: RE: Quality Improvement Act

Here is some suggested language for a new (4)(a):

Subsection (3) does not apply to records or information that are created, collected, reported, aggregated, or organized separately, or exist separately, from a quality improvement activity. ~~Such~~ separate information or a copy ~~thereof~~ reported to a person conducting a quality improvement activity ~~shall~~ not by reason of its reporting be considered privileged and confidential ~~pursuant to subsection 3.~~

-----Original Message-----
From: Callisto, Eric - DRL
Sent: Friday, February 10, 2006 4:50 PM
To: Sweet, Richard; Leitch, Laura; Topinka, Ralph; Kennedy, Debora; Stanford, Matthew
Cc: Berndt, Michael; Gloe, Steve; Schuh, Dennis - DRL
Subject: RE: Quality Improvement Act

Laura and Debora also are available then, so we'll see you at 11:00. Hopefully this will work for Ralph as well. Thanks.

-----Original Message-----
From: Sweet, Richard [mailto:Richard.Sweet@legis.state.wi.us]
Sent: Friday, February 10, 2006 4:21 PM
To: Callisto, Eric - DRL; Leitch, Laura; Topinka, Ralph; Kennedy, Debora; Stanford, Matthew
Cc: Berndt, Michael; Gloe, Steve; Schuh, Dennis - DRL
Subject: RE: Quality Improvement Act

Eric,

Monday at 11 works for me. And if you would like, we can meet in the Leg. Council large conference room (4th floor). I checked and it's available.

Dick

-----Original Message-----
From: Callisto, Eric - DRL [mailto:Eric.Callisto@drl.state.wi.us]
Sent: Friday, February 10, 2006 4:08 PM
To: 'Leitch, Laura'; Sweet, Richard; Topinka, Ralph; Kennedy, Debora; Stanford, Matthew
Cc: Berndt, Michael; Gloe, Steve; Schuh, Dennis - DRL
Subject: RE: Quality Improvement Act

Thanks for the meeting today, and the progress we made. We can be available any time on Monday morning, though my preference is 11:00. As mentioned, we'll assume this is in the same room at LRB.

If you can get us a draft to look at on the specific remaining section, that would be helpful. I'll also work on some suggested language. Thanks.

-----Original Message-----
From: Leitch, Laura [mailto:LLeitch@wha.org]
Sent: Friday, February 10, 2006 11:20 AM
To: eric.callisto@drl.state.wi.us; 'Richard. Sweet (E-mail); Topinka, Ralph; Debora Kennedy (E-mail); Stanford, Matthew

Cc: Borgerding, Eric; Jennifer Stegall (E-mail); 'Randy. Thorson
(E-mail)
Subject: RE: Quality Improvement Act

Attached are the comments from DRL that we'll discuss at the meeting this afternoon.

Thanks!

<<DRLcomments.pdf>>

> -----Original Message-----
> From: Leitch, Laura
> Sent: Thursday, February 09, 2006 2:25 PM
> To: 'eric.callisto@drl.state.wi.us'; 'Richard. Sweet (E-mail);
Topinka,
Ralph; Debora Kennedy (E-mail); Stanford, Matthew
> Cc: Borgerding, Eric; Jennifer Stegall (E-mail); 'Randy. Thorson
(E-mail)
> Subject: Quality Improvement Act
>
> The meeting to resolve the Department of Regulation and Licensing's
> concerns with the QIA is scheduled for tomorrow, Friday, at 1:30 pm.
> Dick Sweet has graciously agreed to host the event in Legislative
> Council conference room at 1 East Main.
>
> Eric, if you have anything in writing before the meeting, it would be
> great if you could shoot it to the group.
>
> Thanks everyone and see you tomorrow.
>
> Laura

Language from Federal Act (for reference):

which—

''(I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or

''(II) are developed by a patient safety organization for the conduct of patient safety activities; and which could result in improved patient safety, health care quality, or health care outcomes; or

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

1. Records and information contained in records that are created, collected, ~~reported,~~ aggregated, or organized by any person for the purpose of reporting to a person conducting quality improvement activity and/are ~~also~~ reported to a person conducting quality improvement activity; or are created, aggregated, or organized as part of a quality improvement activity, if the quality improvement activity ~~that~~ is conducted by any person, organization, department, governing body, or committee, including a committee with representatives from multiple persons, organizations, departments, or governing bodies, that is any of the following:

a. A person, other than a state agency, who is required or authorized by state or federal law, as a condition of accreditation, or under a bylaw, resolution, or policy to conduct the quality improvement activity, or another person who acts on that person's behalf.

b. A person who is charged, authorized, or directed by a person described in subd. 1. a. to conduct the quality improvement activity.

2. Subdivision (3)(a)1. includes a~~A~~ request for records or information made as part of a quality improvement activity ~~described under subd. 1.~~ by a person under subd. 1. conducting the quality improvement activity.

LRB~~s0517/1~~
RLR:cjs:~~jf~~
& DAK

ASSEMBLY SUBSTITUTE AMENDMENT ~~1~~,

TO 2005 ASSEMBLY BILL 993

~~February 7, 2006 – Offered by Representative UNDERHEIM.~~

AN ACT ***to repeal*** 146.37; ***to amend*** 146.55 (7), 187.33 (3) (a) 5., 187.43 (3) (a) 5., 655.27 (1m) (b) and 655.27 (5) (a) 1. and 2.; and ***to repeal and recreate*** 146.38 of the statutes; **relating to:** confidentiality of health care review records and immunity.

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

SECTION 1. 146.37 of the statutes is repealed.

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

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

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

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

2. A health care entity's membership on a medical staff that is organized under by–laws or in another health care entity.

3. A health care entity's participation in a defined network plan, as defined in s. 609.01 (1b).

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

(b) "Health care entity" means any of the following:

1. A health care provider, as defined in s. 146.81 (1), an ambulatory surgery center, as defined in s. 153.01 (1), a home health agency, as defined in s. 50.49 (1) (a), a home health aide, as defined in s. 146.40 (1) (bm), a hospice aide, as defined in s. 146.40 (1) (bp), a nurse's assistant, as defined in s. 146.40 (1) (d), an ambulance service provider, as defined in s. 146.50 (1) (c), an emergency medical technician, as defined in s. 146.50 (1) (e), a first responder, as defined in s. 146.50 (1) (hm), or any other person who is licensed, certified, or registered to provide health care services including mental health services.

2. An individual who is enrolled in an education or training program that the individual must complete in order to obtain credentials required of an individual under subd. 1.

3. A person who is certified as a provider of medical assistance under s. 49.45 (2) (a) 11.

4. A parent organization, subsidiary, or affiliate of a person described under subd. 1. or 3.

(d) "Quality improvement activity" means an evaluation, review, study, assessment, investigation, recommendation, monitoring, corrective action, adverse action, or any other action, which may include one–time, continuous, or periodic data collection, relating to any of the following subjects:

1. The quality of care provided by a health care entity or the quality of services provided by a health care entity that have an impact on care.

2. Morbidity or mortality related to a health care entity.

3. The qualification, competence, conduct, or performance of a health care entity.

4. The cost or use of health care services and resources of a health care entity.

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

6. Compliance with credentialing, accreditation, or regulatory standards for a health care entity and performance of credentialing, accreditation, or regulatory activities. accreditation, licensure, registration, certification,

7. The approval or credentialing of a health care entity.

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

(f) "State agency" ~~means a department, board, examining board, affiliated credentialing board, commission, independent agency, council, or office in the executive branch of state government.~~ has the meaning given for "agency" in s. 16.045 (1) (a)

(2) IMMUNITY FOR ACTS OR OMISSIONS. (a) No person acting in good faith who participates in a quality improvement activity ~~described under sub. (3) (a) 1.~~ is liable for civil damages as a result of any act or omission by the person in the course of the quality improvement activity.

(b) The good faith of any person participating in a quality improvement activity ~~described under sub. (3) (a) 1.~~ shall be presumed in any civil action. Any person who

to which sub. (3) applies

that conducts a quality improvement activity as

asserts that a person has not acted in good faith has the burden of proving that assertion by clear and convincing evidence.

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

1. Records and information contained in records that are created, collected, reported, aggregated, or organized by any person as part of a quality improvement activity that is conducted by any person, organization, department, governing body, or committee, including a committee with representatives from multiple persons, organizations, departments, or governing bodies, that is any of the following:

a. A person, ~~other than a state agency,~~ who is required or authorized by state or federal law, as a condition of accreditation, or under a bylaw, resolution, or policy ~~to conduct the quality improvement activity~~, or another person who acts on that person's behalf. This subdivision unit does not apply to a state agency.

b. A person who is charged, authorized, or directed by a person described in subd. 1. a. to conduct the quality improvement activity.

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

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

(b) Except as provided in sub. (4) (c) and(g), the confidentiality and privilege afforded to ~~records and information~~ under par. (a) is not waived by unauthorized or authorized disclosure of ~~records or information~~.

UNNECESSARY

(c) Records ~~relating to a quality improvement activity~~ described under par. (a) 1. are not subject to inspection or copying under s. 19.35 (1).

(4) EXCEPTIONS TO CONFIDENTIALITY AND PRIVILEGE. (a) Subsection (3) does not apply to records or information created apart from a quality improvement activity that are maintained by or for a health care entity for the particular purpose of diagnosing, treating, or documenting care provided to an individual patient.

(b) Subsection (3) does not prohibit disclosing that a reduction, restriction, suspension, denial, revocation, or failure to renew any item under sub. (1) (a) 1. to 4. has occurred.

required state

(c) A person ~~mandated~~ by ~~Wisconsin~~ or federal law to report may disclose a record or information from a record that is confidential and privileged under sub. (3) to make the ~~mandated~~ report. Subsection (3) does not apply to a record that has been disclosed under this paragraph or to information in the record.

or notifies the health care entity of a propose adver actio again

(d) If a person takes an adverse action against a health care entity as part of a quality improvement activity ~~described under sub. (3) (a) 1., or notifies the health care entity of a proposed adverse action~~, the person shall, upon request by the health care entity, disclose to the health care entity any records in the person's possession relating to the adverse action or proposed adverse action. Records relating to the adverse action are admissible in any criminal, civil, or other judicial or administrative proceeding in which the health care entity contests the adverse action. A person who has authority to take an adverse action against a health care entity as part of a quality improvement activity ~~described under sub. (3) (a) 1.~~ may

to which sub. (3) applies

at any time disclose to the health care entity records relating to a proposed adverse action against the health care entity.

(e) A person conducting a quality improvement activity ~~pursuant to sub. (3)(a) 1.a.~~ may disclose the records and information that are confidential and privileged ~~pursuant to~~ sub. (3).

(f) A person conducting a quality improvement activity ~~pursuant to sub. (3)(a) 1.b.~~ may disclose the records and information that are confidential and privileged ~~pursuant to~~ sub. (3) if there is written authorization to make the disclosure from the person that charged, authorized, or directed the person to conduct the quality improvement activity.

(g) The confidentiality and privilege afforded to records and information under sub. (3) is ~~waived for~~ records that are ~~publicly~~ disclosed ~~under par. (e) or (f) to persons that are not health care entities~~.

(h) A person planning an activity that would be a quality improvement activity ~~under sub. (3)(a) 1.~~ may in advance of the activity designate in writing that sub. (3) ~~shall~~ not apply to the records and information created, collected, reported, aggregated, or organized by any person as part of the designated activity.

(5) Any person who discloses information or releases a record in violation of sub. (3), other than through a good faith mistake, is civilly liable to any person harmed by the disclosure or release.

(6) CONSTRUCTION. This section shall be liberally construed in favor of identifying records and information as confidential, privileged, and inadmissible as evidence.

SECTION 3. 146.55 (7) of the statutes is amended to read:

146.55 **(7)** INSURANCE. A physician who participates in an emergency medical services program under this section or as required under s. 146.50 shall purchase health care liability insurance in compliance with subch. III of ch. 655, except for those acts or omissions of a physician who, as a medical director, ~~reviews~~ as defined in s. 146.50 (1) (j), conducts a quality improvement activity relating to the performance of emergency medical technicians or ambulance service providers, as specified under s. ~~146.37 (1g)~~ 146.38 (2).

SECTION 4. 187.33 (3) (a) 5. of the statutes is amended to read:

187.33 **(3)** (a) 5. Proceedings based upon a cause of action for which the volunteer is immune from liability under s. 146.31 (2) and (3), ~~146.37~~ 146.38 (2), 895.44, 895.48, 895.482, 895.51, or 895.52.

SECTION 5. 187.43 (3) (a) 5. of the statutes is amended to read:

187.43 **(3)** (a) 5. Proceedings based upon a cause of action for which the volunteer is immune from liability under s. 146.31 (2) and (3), ~~146.37~~ 146.38 (2), 895.44, 895.48, 895.482, 895.51, or 895.52.

SECTION 6. 655.27 (1m) (b) of the statutes is amended to read:

655.27 **(1m)** (b) A health care provider who engages in ~~the activities described in s. 146.37 (1g) and (3)~~ a quality improvement activity under 146.38 shall be liable for not more than the limits expressed under s. 655.23 (4) or the maximum liability limit for which the health care provider is insured, whichever limit is greater, if he or she is found to be liable under s. ~~146.37~~ 146.38, and the fund shall pay the excess amount, unless the health care provider is found not to have acted in good faith during those activities and the failure to act in good faith is found by the trier of fact, by clear and convincing evidence, to be both malicious and intentional.

SECTION 7. 655.27 (5) (a) 1. and 2. of the statutes are amended to read:

655.27 **(5)** (a) 1. Any person may file a claim for damages arising out of the rendering of medical care or services or participation in ~~peer review activities~~ a quality improvement activity under s. ~~146.37~~ 146.38 within this state against a health care provider or an employee of a health care provider. A person filing a claim may recover from the fund only if the health care provider or the employee of the health care provider has coverage under the fund, the fund is named as a party in the action, and the action against the fund is commenced within the same time limitation within which the action against the health care provider or employee of the health care provider must be commenced.

2. Any person may file an action for damages arising out of the rendering of medical care or services or participation in ~~peer review activities~~ a quality review activity under s. ~~146.37~~ 146.38 outside this state against a health care provider or an employee of a health care provider. A person filing an action may recover from the fund only if the health care provider or the employee of the health care provider has coverage under the fund, the fund is named as a party in the action, and the action against the fund is commenced within the same time limitation within which the action against the health care provider or employee of the health care provider must be commenced. If the rules of procedure of the jurisdiction in which the action is brought do not permit naming the fund as a party, the person filing the action may recover from the fund only if the health care provider or the employee of the health care provider has coverage under the fund and the fund is notified of the action within 60 days of service of process on the health care provider or the employee of the health care provider. The board of governors may extend this time limit if it finds

that enforcement of the time limit would be prejudicial to the purposes of the fund and would benefit neither insureds nor claimants.

(END)

2/13/06 Mtg: Dick Sweet, Laura Rose, Laura Leitch, Eric Castelo, Mike Bandt, Randy (Underheim's aide), Matt Sanford, Ralph Topinka

LL: What records important to have access to? Concern is if records are gathered for gia process, can obtain gathered material

EC: Don't they want to protect end-product, rather than records contributing?

DS: Will gia have only copy? LL: Possible

Doc. unobtainable from another source that gia – for regulatory purposes } state agency

Ok: { par. (am) – release to st agency of record or info created apart from gia mandated by gia for the entity for gia purp. other than (a), clear + convincing evid – otherwise unavailable.
par. (aa) ok

From Matt Sanford + L. Leitch:
(4)(g) disclosed to gen pub under par (e) or (f)