



2005 ASSEMBLY BILL 830

November 14, 2005 - Introduced by Representatives WIECKERT, VRUWINK, MUSSER, GRONEMUS, BIES, SCHNEIDER, HAHN, JESKEWITZ, VOS, TOWNSEND, McCORMICK, SHILLING, ALBERS, LEHMAN, GUNDERSON, KREIBICH, GHELOW, WASSERMAN, UNDERHEIM, KRAWCZYK, OWENS, ZEPNICK, BOYLE, KESTELL, VAN ROY, AINSWORTH, NELSON, STRACHOTA, OTT, NASS and BALLWEG, cosponsored by Senators A. LASEE, BRESKE, OLSEN, RISSER, LEIBHAM, HANSEN, DARLING, ERPENBACH, LASSA, COWLES and KEDZIE. Referred to Committee on Health.

REGENERATE

✓+

1 AN ACT *to repeal* 157.06 (11) and 157.06 (12); *to amend* 157.06 (2) (j), 157.06 (4)
2 (title), 157.06 (4) (am) (intro.), 157.06 (4) (b) and 157.06 (5) (bm); *to repeal and*
3 *recreate* 157.06 (title); and *to create* 157.06 (4m) and 157.06 (4r) of the
4 statutes; **relating to:** anatomical gifts and the powers and duties of coroners
5 and medical examiners.

granting rule-making authority,
and providing an exemption from
emergency rule procedure

Analysis by the Legislative Reference Bureau

at the time

Currently, an individual who is at least 18 years of age may make an anatomical gift (donation of all or part of his or her body to take effect ~~upon~~ or after he or she irreversibly ceases circulatory and respiratory functions or all functions of the brain). Also, certain members of a decedent's family or his or her health care agent under a power of attorney for health care may make an anatomical gift of all or a part of the decedent's body. If a decedent is within the custody of a coroner or medical examiner and there is no evidence that the decedent made or refused to make an anatomical gift, under certain circumstances the coroner or medical examiner may release and permit the removal of a part from the decedent's body for use in transplantation or therapy.

under an order of priority

This bill creates requirements related to removal of a body part from a decedent who is within the jurisdiction of a coroner or medical examiner and who has made an anatomical gift or whose family or health care agent has made an anatomical gift of all or part of the decedent's body. For such a person, a physician may remove a vascularized organ (a heart, lung, liver, pancreas, kidney, intestine, or other organ

Substitute amendment

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INSERT ANAL 2

that requires the continuous circulation of blood to remain useful for purposes of transplantation) within a time period in which the organ may be preserved for purposes of transplantation if (1) ~~the coroner or medical examiner or his or her designee is first provided notice of the intended removal~~; and (2) the coroner or medical examiner or his or her designee has the opportunity to be present during the vascularized organ's removal if in his or her judgment the organ may be necessary in determining the cause of death. However, if, in the judgment of the coroner, medical examiner, or designee, the organ may be necessary in determining the cause of death, the coroner, medical examiner, or designee may order a biopsy of the vascularized organ or, if he or she is present during the physician's scheduled removal, may deny removal. If a biopsy is ordered or removal is denied, the coroner, medical examiner, or designee must specify any reason in writing. Parts or all of the decedent's body that are anatomical gifts, other than vascularized organs, may be removed by a physician or technician as authorized by the coroner, medical examiner, or designee with jurisdiction over the decedent. A physician or technician who removes cardiovascular tissue from a decedent must, upon request by a coroner or medical examiner, file a report with the coroner or medical examiner. The agency recovering the part must maintain a permanent record of the name of the decedent, the name of any person who made an anatomical gift on behalf of the decedent, the date and purpose of the document of gift, the part removed, and the name of the person to whom the part was released. The agency must, upon request, make this record available to the coroner or medical examiner.

INSERT ANAL 1

as part of the death report

INSERT ANAL 3

Substitute amendment

The ~~bill~~ also requires, for a decedent who is within the custody of a coroner or medical examiner and whose death occurred in a hospital, that any release of the decedent as a potential tissue donor be to the tissue bank with which the hospital has an agreement, as required under federal law. A decedent whose death occurred outside a hospital and who is within the custody of a coroner or medical examiner may be referred as a potential tissue donor to a single tissue bank if the county board has an agreement with only that tissue bank or on an equal rotating basis to those tissue banks with which the county board has agreements. The tissue bank or tissue banks must be selected by the county board under a request-for-proposals process and must be registered and accredited.

INSERT ANAL 4

For further information see the ~~state and local~~ fiscal estimate, which will be printed as an appendix to this bill.

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

- 1 SECTION 1. 157.06 (title) of the statutes is repealed and recreated to read:
- 2 157.06 (title) **Anatomical gifts.**
- 3 SECTION 2. 157.06 (2) (j) of the statutes is amended to read:

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1 157.06 (2) (j) In the absence of contrary indications by the donor, an anatomical
2 gift of a part of a human body is neither a refusal to give other parts of the body nor
3 a limitation on an anatomical gift under sub. (3) or on a removal or release of other
4 parts of the body under sub. (4) or (4m).

5 **SECTION 3.** 157.06 (4) (title) of the statutes is amended to read:

6 157.06 (4) (title) ~~NOTIFICATION AND AUTHORIZATION~~ AUTHORIZATION BY CORONER
7 OR MEDICAL EXAMINER; DECEDENT NOT A DONOR.

8 **SECTION 4.** 157.06 (4) (am) (intro.) of the statutes is amended to read:

9 157.06 (4) (am) (intro.) The coroner or medical examiner may release and
10 permit the removal of a part from, a decedent specified in par. (ag) within that
11 official's custody, for transplantation or therapy, if all of the following apply:

12 **SECTION 5.** 157.06 (4) (b) of the statutes is amended to read:

13 157.06 (4) (b) ~~An official releasing, and permitting~~ A coroner or medical
14 examiner who releases, and permits the removal of a part of, a human body under
15 this subsection shall maintain a permanent record of the name of the decedent, the
16 name of the person making the request, the date and purpose of the request, the part
17 of the body requested, and the name of the person to whom it was released.

18 **SECTION 6.** 157.06 (4m) of the statutes is created to read:

19 157.06 (4m) AUTHORIZATION BY CORONER OR MEDICAL EXAMINER; DECEDENT A
20 DONOR. (a) Subject to par. (b), for a decedent who meets the criteria for a
21 determination of death under s. 146.71, who is a donor or of whom an anatomical gift
22 has been made under sub. (3), and who is within the jurisdiction of a coroner or
23 medical examiner under ch. 979, any vascularized organ that is an anatomical gift
24 may be removed by a physician, within a time period compatible with preservation
25 of the organ for purposes of transplantation, if all of the following take place:

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SECTION 6

1. The coroner or medical examiner or his or her designee is first provided notice of the intended removal.

INSERT 4-2

2. The coroner or medical examiner or his or her designee has the opportunity to be present during the physician's removal of the vascularized organ if, in the judgment of the coroner, medical examiner, or designee, the organ may be necessary in determining the cause of death.

Use 20

the coroner, medical examiner, or designee

(b) If, in the judgment of the coroner, medical examiner, or designee specified in par. (a) the vascularized organ may be necessary in determining the cause of death, he or she may order a biopsy of the vascularized organ or, if he or she is present during the physician's scheduled removal, may deny removal.

INSERT 4-10

If the biopsy is ordered or the removal is denied, the coroner, medical examiner, or designee shall specify, in writing as part of any death report required under ch. 979, any reasons for determining that the organ may be involved in the cause of death.

(c) For a decedent specified under par. (a), any part other than a vascularized organ that is an anatomical gift may be removed by a physician or technician, within a time period compatible with preservation of the part for purposes of transplantation, as authorized by the coroner, medical examiner, or designee with jurisdiction over the decedent.

INSERT 4-18

(d) A physician or technician who removes cardiovascular tissue from a decedent under this subsection shall, upon request of the coroner or medical examiner, file with the coroner or medical examiner a report detailing the condition of the cardiovascular tissue and its relationship to the cause of death. The report may include a biopsy or medically approved sample, if available, from the part.

(e) If a coroner or medical examiner or his or her designee releases and permits the removal of a part under this subsection, the recovering agency shall maintain a

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1 permanent record of the name of the decedent, the name of the person, if any, who
2 made an anatomical gift under sub. (3), the date and purpose of the document of gift,
3 the part of the body removed, and the name of the person to whom the part was
4 released. The recovering agency shall make the record under this paragraph
5 available, upon request, to the coroner or medical examiner.

6 SECTION 7. 157.06 (4r) of the statutes is created to read:

7 157.06 (4r) AUTHORIZATION BY CORONER OR MEDICAL EXAMINER; DONEE. (a) If a
8 decedent is within the custody of a coroner or medical examiner, and the death
9 occurred in a hospital, any release by the hospital of the decedent as a potential tissue donor shall
10 be to the tissue bank with which the hospital has an agreement under 42 CFR 482.45

11 (a) (2).

12 (b) If a decedent is within the custody of a coroner or medical examiner, and the
13 death occurred outside a hospital, any referral of the decedent as a potential tissue
14 donor by the coroner or medical examiner shall be made under the following
15 conditions:

16 1. The applicable county board shall have used a request-for-proposals process
17 that considers a tissue bank's history, services, and tissue distribution record in
18 selecting the tissue bank or tissue banks to which the coroner or medical examiner
19 shall refer the decedent as a potential tissue donor.

20 2. a. If the applicable county board has entered into an agreement with only
21 one tissue bank following the request-for-proposals process, the coroner or medical
22 examiner shall refer the decedent as a potential tissue donor in accordance with the
23 agreement.

24 b. If the applicable county board has entered into agreements with more than
25 one tissue bank following the request-for-proposals process, the coroner or medical

INSERT 5-11

and the coroner or medical examiner refers

any such referral

1.

and any other criteria required for consideration by the corporation counsel of the applicable county

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SECTION 7

1 examiner shall refer decedents as potential tissue donors on an equal rotating basis
2 to the tissue banks.

INSERT 6-2

3 3. Tissue banks under this paragraph shall be accredited by the American
4 Association of Tissue Banks and registered with the federal Food and Drug
5 Administration.

or audited at least once every 2 years by an organization that is accredited by the

SECTION 8. 157.06 (5) (bm) of the statutes is amended to read:

American Association of Tissue Banks

7 157.06 (5) (bm) If at or near the time of death of a patient a hospital knows that
8 an anatomical gift of all or a part of the patient's body has been made under sub. (3)
9 (a), that a release and removal of a part of the patient's body has been permitted
10 under sub. (4) or (4m) or that a patient or an individual identified as in transit to the
11 hospital is a donor, the hospital shall notify the donee if one is named and known to
12 the hospital. If a donee is neither named nor known to the hospital, the hospital shall
13 notify an appropriate procurement organization. The hospital shall cooperate in the
14 implementation of the anatomical gift or release and removal of a part of the body
15 of the patient or individual.

INSERT 6-15

16 SECTION 9. 157.06 (11) of the statutes is repealed.

17 SECTION 10. 157.06 (12) of the statutes is repealed.

18 (END)

INSERT 6-17

D-NOTE

2005-2006 DRAFTING INSERT
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRBs0425/7ins P1
.....

~~NO #~~
INSERT ANAL 1

immediately after the hospital in which the decedent is located contacts the organ procurement organization concerning the potential donation, the organ procurement organization provides notice, by oral conversation, of the intended removal to the coroner or medical examiner or his or her designee and provides notice of the intended removal to the district attorney or his or her designee. ✓

~~NO #~~
INSERT ANAL 2

If denial of removal is a possibility, the organ procurement organization may consult with a forensic pathologist, if available, as to the pathologist's opinion concerning the necessity of the organ in determining the cause of death. ✓

~~NO #~~
INSERT ANAL 3

A physician or technician who removes an organ from a decedent must complete a form, as specified by the Department of Health and Family Services (DHFS) by rule, and transmit the completed form to the coroner or medical examiner. The secretary of health and family services must appoint an advisory committee to assist DHFS in prescribing, by rule, this form. ✓

~~NO #~~
INSERT ANAL 4

However, if that tissue bank is unwilling to receive the release, the tissue bank must notify the coroner or medical examiner, who then may notify concerning the availability any other tissue bank with which the coroner or medical examiner has an agreement. ✓ A tissue bank that is so notified, if it is willing to receive the release, must notify an available member of the decedent's family or the decedent's health care agent, under the order of priority, to request that the member or agent make an anatomical gift of all or part of the decedent's body. In such a case, the hospital in which the decedent's death occurred must either enter into a written agreement with this tissue bank authorizing the tissue bank to remove the tissue in the hospital or release the decedent to the tissue bank for removal of the tissue in another place. ✓

✕ If a decedent is within the custody of a coroner or medical examiner, the death occurred *outside* a hospital, and the coroner or medical examiner refers the decedent as a potential tissue donor, the substitute amendment requires that any such referral be made to one or more tissue banks with which the coroner or medical examiner has a written agreement. The agreement may be made only after the coroner or medical examiner has considered a number of factors concerning the tissue bank, and the agreement is subject to review and approval by the corporation counsel of the applicable county and, under a passive review process, by the applicable county board. Any tissue bank to which referral is made must be accredited by the American Association of Tissue Banks or audited at least once every two years by an organization that is accredited by the American Association of Tissue Banks. ✓

INSERT 4-2

- 1 1. Immediately after the administrator of the hospital in which the donor or
2 potential donor is located, or a representative designated by the administrator,

1 contacts the organ procurement organization designated for the region of which the
2 hospital is a part concerning the potential donation, the organ procurement
3 organization shall, by oral conversation, provide notice of the intended removal to
4 the coroner or medical examiner or his or her designee and shall provide notice to the
5 district attorney or his or her designee. ✓

INSERT 4-10

6 *NOT* If denial of removal is a possibility, the organ procurement organization may
7 consult with a forensic pathologist, if available, as to the pathologist's opinion
8 concerning the necessity of the organ in determining the cause of death. ✓

INSERT 4-18

9 (cm) A physician or technician who removes an organ from a decedent under
10 this subsection shall complete a form, as specified in sub. (9m), and transmit the
11 completed form to the coroner or medical examiner with jurisdiction over the
12 decedent.

INSERT 5-11

13 *NOT* However, if such a tissue bank is unwilling to receive the release, the tissue
14 bank shall so notify the coroner or medical examiner.

15 2. Upon receipt of a notification under subd. 1., the coroner or medical examiner
16 may notify any other tissue bank with which the coroner or medical examiner has
17 an agreement under par. (b) of the availability of the decedent as a potential tissue
18 donor.

19 3. Upon receipt of a notification under subd. 2., the tissue bank so notified, if
20 willing to receive the release, shall contact an available individual, under the priority
21 established in sub. (3) (a), to request that the individual make an anatomical gift of
22 all or a part of the decedent's body. ✓

1 4. If subds. 2. and 3. apply, the hospital in which the decedent's death occurred
2 shall do one of the following:

3 a. Enter into a written agreement with the tissue bank specified in subd. 3. that
4 authorizes the tissue bank to remove the decedent's tissue in the hospital.

5 b. Release the decedent to the tissue bank specified in subd. 3. for removal of
6 the decedent's tissue in a place other than in the hospital.

INSERT 6-2

7 1. Subject to subd. 2., the coroner or medical examiner, after considering a
8 tissue bank's history, services, traditional referral patterns, geographic service area,
9 and tissue distribution record and any other criteria required for consideration by
10 the corporation counsel of the applicable county, enters into a written agreement
11 with one or more tissue banks to which the coroner or medical examiner shall refer
12 decedents as potential tissue donors.

13 2. Any agreement under subd. 1. is subject to review and approval by the
14 following:

15 a. The corporation counsel of the applicable county.

16 b. The county board of the applicable county. If, within 60 days after any
17 approval by the corporation counsel and transmittal of the agreement to the county
18 board, the county board takes no action, the agreement is approved. However, if
19 within that period the county board requests review, the agreement is approved only
20 if the county board approves it or takes no action on it.

INSERT 6-15

21 **SECTION 1.** 157.06 (9m) of the statutes is created to read:

1 157.06 (9m) ORGAN REMOVAL FORM; RULES. The department of health and family
2 services shall promulgate rules prescribing an organ removal form for use under sub.
3 (4m) (cm).

INSERT 6-17

4 **SECTION 2.** 979.01 (5) of the statutes is created to read:

5 979.01 (5) Under the circumstances specified in s. 157.06 (4r) (a), a coroner or
6 medical examiner may release custody of a decedent whose death occurred in a
7 hospital.

8 **SECTION 3. Nonstatutory provisions.**

9 (1) ORGAN REMOVAL FORM; ADVISORY COMMITTEE; EMERGENCY RULES. (a) The
10 secretary of health and family services shall appoint an advisory committee under
11 section 15.04 (1) (c) of the statutes that shall include coroners, medical examiners,
12 organ procurement organization personnel, and district attorneys, to assist the
13 department of health and family services in prescribing, by rule, an organ removal
14 form for use under section 157.06 (4m) (cm) of the statutes, as created by this act.

15 (b) After consulting with the advisory committee under paragraph (a), by the
16 first day of the 4th month beginning after the effective date of this subsection, the
17 department of health and family services shall, using the procedure under section
18 227.24 of the statutes, promulgate the rules required under section 157.06 (9m) of
19 the statutes, as created by this act, for the period before the effective date of the
20 permanent rules promulgated under section 157.06 (9m) of the statutes, as created
21 by this act, but not to exceed the period authorized under section 227.24 (1) (c) and
22 (2) of the statutes. Notwithstanding section 227.24 (1) (a), (2) (b), and (3) of the
23 statutes, the department is not required to provide evidence that promulgating a rule
24 under this paragraph as an emergency rule is necessary for the preservation of the

✓ create A.R. 1
✓ use A.R. 1

- 1 public peace, health, safety, or welfare and is not required to provide a finding of
- 2 emergency for a rule promulgated under this paragraph. ✓

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRBs0425/2dn

DAK.....

Imk

PI

(date)

To Representative Wieckert:

1. This substitute amendment is drafted from the December 13, 2005, memo of Dick Sweet (Dick Sweet memo), from a December 20, 2005, e-mail to Dick from Pete Christianson (Christianson e-mail) that summarizes comments received from numerous sources, and from a conference call of December 20, 2005.
2. I am drafting this material in preliminary form, to permit it to be reviewed as quickly as possible and because I have not yet received from the Wisconsin Hospitals Association confirmation on certain changes to s. 157.06 (4r) (a) that Jodi Bloch proposed in her e-mail to Scott Becher of December 15, 2005, as contained in point E. of the Christianson e-mail.
3. In s. 157.06 (4r) (b), this substitute amendment requires, for a death that occurs outside a hospital, that any referral to a tissue bank made by a coroner or medical examiner be to a tissue bank with which the coroner or medical examiner has a written agreement after having considered certain factors. Is it contemplated that each referral will require a separate agreement? If not, how do you intend that this requirement affect any current agreements that coroners or medical examiners may have with tissue banks? If you intend that those agreements be reconsidered in light of the substitute amendment's requirements, there may be an impairment of contract problem. One way to deal with such a problem would be to apply the requirement only to new contracts or to renewals of existing contracts. Please advise.
4. I drafted s. 157.06 (4m) (cm) as a response to the fourth bullet point under *Removal of Organs* of the Dick Sweet memo. If, however, this provision was intended to replace, rather than augment, any part of s. 157.06 (4m) (such as s. 157.06 (4m) (d), which is written to apply to cardiovascular tissue and not to organs), please let me know and I will redraft.

Please let me know if I may provide further assistance with this draft.

Debora A. Kennedy
Managing Attorney
Phone: (608) 266-0137
E-mail: debora.kennedy@legis.state.wi.us

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRBs0425/1dn
DAK:lmk:ch

December 30, 2005

To Representative Wieckert:

1. This substitute amendment is drafted from the December 13, 2005, memo of Dick Sweet (Dick Sweet memo), from a December 20, 2005, e-mail to Dick from Pete Christianson (Christianson e-mail) that summarizes comments received from numerous sources, and from a conference call of December 20, 2005.
2. I am drafting this material in preliminary form, to permit it to be reviewed as quickly as possible and because I have not yet received from the Wisconsin Hospitals Association confirmation on certain changes to s. 157.06 (4r) (a) that Jodi Bloch proposed in her e-mail to Scott Becher of December 15, 2005, as contained in point E. of the Christianson e-mail.
3. In s. 157.06 (4r) (b), this substitute amendment requires, for a death that occurs outside a hospital, that any referral to a tissue bank made by a coroner or medical examiner be to a tissue bank with which the coroner or medical examiner has a written agreement after having considered certain factors. Is it contemplated that each referral will require a separate agreement? If not, how do you intend that this requirement affect any current agreements that coroners or medical examiners may have with tissue banks? If you intend that those agreements be reconsidered in light of the substitute amendment's requirements, there may be an impairment of contract problem. One way to deal with such a problem would be to apply the requirement only to new contracts or to renewals of existing contracts. Please advise.
4. I drafted s. 157.06 (4m) (cm) as a response to the fourth bullet point under *Removal of Organs* of the Dick Sweet memo. If, however, this provision was intended to replace, rather than augment, any part of s. 157.06 (4m) (such as s. 157.06 (4m) (d), which is written to apply to cardiovascular tissue and not to organs), please let me know and I will redraft.

Please let me know if I may provide further assistance with this draft.

Debora A. Kennedy
Managing Attorney
Phone: (608) 266-0137
E-mail: debora.kennedy@legis.state.wi.us

Kennedy, Debora

From: Becher, Scott
Sent: Tuesday, January 03, 2006 5:16 PM
To: Kennedy, Debora
Subject: FW: Suggested revisions to AB 830 substitute amendment

-----Original Message-----

From: Christianson, Peter C. [mailto:PCC@quarles.com]
Sent: Tuesday, January 03, 2006 5:15 PM
To: Becher, Scott
Cc: aoconnor@murphydesmond.com; Dalessandro Anthony M; Maroney Lisa A.; Laura Leitch
Subject: Suggested revisions to AB 830 substitute amendment

Scott -

Here is a summary of the suggested changes to the substitute amendment to AB 830 which we (Dr. D'Alessandro, Lisa Maroney, Laura Leitch, you, and I) discussed this afternoon:

* See later change
1. In the analysis, we believe that many, if not all, references to "decedent" should be changed to "potential donor." Rationale: The donation process often begins before the formal declaration of death is made.

✓ 2. On page 4, line 18, strike the words "the administrator of". On line 19, strike ", or a representative designated by the administration,". Rationale: There is no need to identify with specificity which hospital officials have the power to contact an OPO.

* 3. On page 4, line 22, delete the words "intended referral" and substitute "referral of the potential donor". Rationale: Of the 50-70 referrals which an OPO may receive each month, only about 12-15 may proceed to donation.

✓ 4. On page 6, line 14, change the title of the newly-created section to: "AUTHORIZATION BY CORONER OR MEDICAL EXAMINER: DECEDENT A TISSUE DONOR". Rationale: This more clearly explains the differences between Section 157.06 (4m) and Section 157.06 (4r).

✓ 5. On page 6, line 16, delete the words "by the hospital". Rationale: According to the WHA, the hospital technically never releases a decedent.

✓ 6. On page 7, delete lines 3 through 8 and substitute:

"4. If subds. 2. and 3. apply, the coroner or medical examiner may remove the body from the hospital in which the body is located."

Rationale: Gives the coroner the direct authority to take custody of the decedent in order to facilitate the donation.

✓ 7. On page 7, line 10, after "hospital" insert "or if the decedent was removed from a hospital". Rationale: Clearly delineates when a tissue bank under contract with a coroner or medical examiner may be utilized.

✓ 8. On page 8, delete lines 22-25. Rationale: We do not believe this section is needed.

✓ 9. On page 9, line 4, after "coroners," insert "forensic pathologists,". Rationale: Include forensic pathologists on the DHFS committee.

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transmission from your system. In addition, in order to comply with Treasury Circular 230, we are required to inform you that unless we have specifically stated to the contrary in writing, any advice we provide in this email or any attachment concerning federal tax issues or submissions is not intended or written to be used, and cannot be used, to avoid federal tax penalties.

Kennedy, Debora

From: Becher, Scott
Sent: Wednesday, January 04, 2006 11:14 AM
To: Kennedy, Debora
Subject: FW: REVISED suggested revisions to AB 830 substitute amendment

-----Original Message-----

From: Christianson, Peter C. [mailto:PCC@quarles.com]
Sent: Wednesday, January 04, 2006 10:58 AM
To: Becher, Scott
Cc: aconnor@murphydesmond.com; Dalessandro Anthony M; Maroney Lisa A.; Laura Leitch
Subject: REVISED suggested revisions to AB 830 substitute amendment

Scott -

NOTE: This summary has been revised following receipt of an e-mail from Dr. D'Alessandro this morning. We misunderstood a point he made in what was #1 in the earlier e-mail.

Here is a summary of the suggested changes to the substitute amendment to AB 830 which we (Dr. D'Alessandro, Lisa Maroney, Laura Leitch, you, and I) discussed this afternoon:

1. In the analysis (page 2, line 9), we believe that word "decedent" should be changed to "potential donor." Rationale: The donation process often begins before the formal declaration of death is made. (NOTE CHANGE HERE!)
2. On page 4, line 18, strike the words "the administrator of". On line 19, strike ", or a representative designated by the administration,". Rationale: There is no need to identify with specificity which hospital officials have the power to contact an OPO.
3. On page 4, line 22, delete the words "intended referral" and substitute "referral of the potential donor". Rationale: Of the 50-70 referrals which an OPO may receive each month, only about 12-15 may proceed to donation.
4. On page 6, line 14, change the title of the newly-created section to: "AUTHORIZATION BY CORONER OR MEDICAL EXAMINER: DECEDENT A TISSUE DONOR". Rationale: This more clearly explains the differences between Section 157.06 (4m) and Section 157.06 (4r).
5. On page 6, line 16, delete the words "by the hospital". Rationale: According to the WHA, the hospital technically never releases a decedent.
6. On page 7, delete lines 3 through 8 and substitute:

"4. If subds. 2. and 3. apply, the coroner or medical examiner may remove the body from the hospital in which the body is located."

Rationale: Gives the coroner the direct authority to take custody of the decedent in order to facilitate the donation.
7. On page 7, line 10, after "hospital" insert "or if the decedent was removed from a hospital". Rationale: Clearly delineates when a tissue bank under contract with a coroner or medical examiner may be utilized.
8. On page 8, delete lines 22-25. Rationale: We do not believe this section is needed.
9. On page 9, line 4, after "coroners," insert "forensic pathologists,". Rationale: Include forensic pathologists on the DHFS committee.

From Dr. D'Alessandro:
ok to use "donor,
potential decedent, or
decedent"

This electronic mail transmission and any attachments are confidential and may be privileged. They should be read or retained only by the intended recipient. If you have received this transmission in error, please notify the sender immediately and delete the transmission from your system. In addition, in order to comply with Treasury Circular 230, we are required to inform you that unless we have specifically stated to the contrary in writing, any advice we provide in this email or any attachment concerning federal tax issues or submissions is not intended or written to be used, and cannot be used, to avoid federal tax penalties.

Kennedy, Debora

From: Becher, Scott
Sent: Wednesday, January 04, 2006 1:02 PM
To: Kennedy, Debora
Subject: FW: REVISED suggested revisions to AB 830 substitute amendment

-----Original Message-----

From: Dalessandro Anthony M [mailto:am.dalessandro@hosp.wisc.edu]
Sent: Wednesday, January 04, 2006 12:29 PM
To: Leitch, Laura; Christianson, Peter C.; Becher, Scott
Cc: Maroney Lisa A.
Subject: RE: REVISED suggested revisions to AB 830 substitute amendment

Scott, I think this language sounds good. Tony

From: Leitch, Laura [mailto:LLeitch@wha.org]
Sent: Wed 1/4/2006 11:53 AM
To: Christianson, Peter C.
Cc: Dalessandro Anthony M; Maroney Lisa A.
Subject: RE: REVISED suggested revisions to AB 830 substitute amendment

I just spoke with Dick Sweet. He forwarded some comments to Wieckert this morning (said they're just technical).

We walked through some of the comments from the below email, and he suggested amending the bill beginning on page 7, line 9 to read something like:

"If the decedent is within the custody of the coroner or the medical examiner, under the circumstances described in (a)4 ^{or} the death occurred outside a hospital, and the coroner or medical examiner refers the decedent as a potential tissue donor, any such referral shall be made under the following conditions:"

He thought it made it clearer that (b) would only apply when the death occurred outside a hospital. I think he's right agree?

Laura

No; (a)4. refers to (a)2.+3., wh/ apply w/in a hospital

From: Christianson, Peter C. [mailto:PCC@quarles.com]
Sent: Wed 1/4/2006 10:57 AM
To: Becher, Scott
Cc: aoconnor@murphydesmond.com; Dalessandro Anthony M; Maroney, Lisa; Leitch, Laura
Subject: REVISED suggested revisions to AB 830 substitute amendment

Scott -

NOTE: This summary has been revised following receipt of an e-mail from Dr. D'Alessandro this morning. We misunderstood a point he made in what was #1 in the earlier e-mail.

Here is a summary of the suggested changes to the substitute amendment to AB 830 which we (Dr. D'Alessandro, Lisa Maroney, Laura Leitch, you, and I) discussed this afternoon:

1. In the analysis (page 2, line 9), we believe that word "decedent" should be changed

to "potential donor." Rationale: The donation process often begins before the formal declaration of death is made. (NOTE CHANGE HERE!)

2. On page 4, line 18, strike the words "the administrator of". On line 19, strike ", or a representative designated by the administration,". Rationale: There is no need to identify with specificity which hospital officials have the power to contact an OPO.

3. On page 4, line 22, delete the words "intended referral" and substitute "referral of the potential donor". Rationale: Of the 50-70 referrals which an OPO may receive each month, only about 12-15 may proceed to donation.

4. On page 6, line 14, change the title of the newly-created section to: "AUTHORIZATION BY CORONER OR MEDICAL EXAMINER: DECEDENT A TISSUE DONOR". Rationale: This more clearly explains the differences between Section 157.06 (4m) and Section 157.06 (4r).

5. On page 6, line 16, delete the words "by the hospital". Rationale: According to the WHA, the hospital technically never releases a decedent.

6. On page 7, delete lines 3 through 8 and substitute:

"4. If subds. 2. and 3. apply, the coroner or medical examiner may remove the body from the hospital in which the body is located."

Rationale: Gives the coroner the direct authority to take custody of the decedent in order to facilitate the donation.

7. On page 7, line 10, after "hospital" insert "or if the decedent was removed from a hospital". Rationale: Clearly delineates when a tissue bank under contract with a coroner or medical examiner may be utilized.

8. On page 8, delete lines 22-25. Rationale: We do not believe this section is needed.

9. On page 9, line 4, after "coroners," insert "forensic pathologists,". Rationale: Include forensic pathologists on the DHFS committee.

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Kennedy, Debora

From: Becher, Scott
Sent: Wednesday, December 28, 2005 3:21 PM
To: Kennedy, Debora
Subject: FW: Email that I sent to Alice

Debora-

I agree with this..

Can we make this change yet?

Scott Becher

-----Original Message-----

From: Christianson, Peter C. [mailto:PCC@quarles.com]
Sent: Wednesday, December 28, 2005 2:59 PM
To: Becher, Scott
Cc: Maroney Lisa A.; Dalessandro Anthony M
Subject: RE: Email that I sent to Alice

Scott -

I have talked to Lisa Maroney. She and I concur that the substitute amendment should do what the Wisconsin Hospital Association suggests as alternative #1 -- the substitute should be silent on the subject of secondary donation if the coroner no longer has control over the body. We cannot put hospitals in the position of violating federal law.

Since time is of the essence, we would appreciate your telling Debora Kennedy to draft it in this manner. We believe it is essential to get the draft ready for action by the Assembly Health Committee no later than January 10, so that the bill can be taken up by the Assembly during January.

Thank you for bringing this issue to our attention and for your continuing diligence on this very important bill.

-----Original Message-----

From: Becher, Scott [mailto:Scott.Becher@legis.state.wi.us]
Sent: Wednesday, December 28, 2005 12:15 PM
To: Christianson, Peter C.; la.maroney@hosp.wisc.edu
Subject: FW: Email that I sent to Alice

FYI..

Call Me..

Scott Becher
 Rep. Wieckert

-----Original Message-----

From: Bloch, Jodi [mailto:jbloch@wha.org]
Sent: Wednesday, December 28, 2005 12:03 PM
To: Becher, Scott
Cc: Leitch, Laura
Subject: FW: Email that I sent to Alice

Scott,

I just got an email back saying that Alice is out until January 3. Here's the excerpt I emailed her today along with the Hall Render Alert regarding this issue.

"Alice,

*12/28: Talked w/ Scott - had already sent draft to editing; there likely are other changes w/ should also be made, so will defer making this to the next redraft.
 DAK*

Your were going to talk with the coroners again per your email below to Laura on last Thursday. I just wanted to forward you another piece of information that you may want to share. It is a health law alert from Hall Render regarding this issue. In discussing cases where the death occurred in a hospital, on the second page, in the second paragraph note under 4) "under no circumstances should a hospital allow the ME or Coroner to make a direct referral to the OPO or a tissue recovery agency as this would be in violation of the Federal regulations governing organ, tissue and eye procurement."

This is precisely why we need to remain silent on the issue of secondary donation if the coroner no longer has control over the body OR we must give the coroner explicit power to take control of the body again, because otherwise the hospital will be in violation of federal regulations as described in the alert. Let us know what your folks think. Thanks & Happy Holidays! - Jodi"

Jodi Bloch
Vice President-Government Affairs
Wisconsin Hospital Association
608/268-1836
jbloch@wha.org

Scott,

This is the email that WHA's Laura Leitch sent to Alice per Debra Kennedy's call last Thursday.

"If the coroner/ME retains custody, then no problem. If not, we either need to be silent about it (it would happen so infrequently that (1) the coroner released custody of the body AND (2) the hospital's tissue bank refused the donation AND (3) another tissue bank that doesn't have a contract with the hospital would accept the donation) or we need language that would permit the hospital to give custody of the body back to the coroner.

We thought the coroners/MEs didn't want the statute to address the issue re the authority to return custody to them. If they're okay with that, that's fine. Is that what they mean?

Laura"

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Gina Reese - Contract issue
Referral issue

Kennedy, Debora

From: Becher, Scott
Sent: Wednesday, January 04, 2006 3:56 PM
To: Kennedy, Debora
Subject: FW: AB 830 Draft

From: Gina Reese [mailto:Gina_Reese@mtf.org]
Sent: Wednesday, January 04, 2006 3:58 PM
To: Becher, Scott
Cc: Forbes McIntosh; Michelle Mettner; Dalessandro Anthony M
Subject: AB 830 Draft

Hello Scott,

Thanks so much for all of the work you've put into AB 830! I'd like to respond to a few issues:

1. We've spoken with WHA and support their recommendation to remove lines 3 – 8 on page 7, and replace with a statement added to page 7 line 10 as follows: "death occurred outside a hospital, under circumstances described in (4r) (a), and the coroner..."

This addition would tie both in-hospital and out-hospital coroner referrals to the public selection process for tissue banks, without opening up a loop hole for a coroner/ME to circumvent the hospital's selected tissue bank.

2. We understand that a recommendation has been put forward to "grandfather" in existing "agreements" or "contracts" with a five year extension. First, through all of the testimony and subsequent meetings the coroners have maintained that they do not have "contracts" – they only have informal "agreements" that outline the working relationship between the coroner and the tissue bank. Therefore, the contract requirement in the legislation will not put them in any jeopardy with existing "contracts". Second, this grandfather arrangement would allow the coroners to completely circumvent the public and transparent process we have been working so diligently to implement. MTF will not support a grandfather clause.

Thanks, and please let me or the folks at Broydrick know if you have any further questions.

Best Wishes and Happy New Year!

Gina Groezinger Reese
Assoc. Regional Director
MTF
Office: 608-764-1390

Kennedy, Debora

From: Becher, Scott
Sent: Wednesday, January 04, 2006 11:13 AM
To: Kennedy, Debora; Peter C. Christianson (pcc@quarles.com); Lisa Maroney (la.maroney@hosp.wisc.edu); Anthony M. D'Alessandro (tony@tx.surgery.wisc.edu)
Subject: FW: Draft review: LRB 05s0425/P1 Topic: Anatomical gifts and powers and duties of coroners and medical examiners

From: Bill McCoshen [mailto:bill.mccoshen@capitolconsultants.net]
Sent: Wednesday, January 04, 2006 10:30 AM
To: Becher, Scott
Cc: ssabo@atsfoundation.org; lshinstine@charter.net; rturner@lifeshareok.org; wem@dewittross.com
Subject: RE: Draft review: LRB 05s0425/P1 Topic: Anatomical gifts and powers and duties of coroners and medical examiners

Scott,

My client and I have reviewed the draft from Debora Kennedy. Overall, she did a nice job of capturing the agreement that was made between the stakeholders at our last meeting.

However, we agree with Debora that something should be said about "existing contracts" between a coroner or medical examiner and a tissue bank. I don't believe anyone at the stakeholder meetings contemplated a retrospective process for existing contracts. In other words, we need to come up with language that would grandfather any agreement that existed prior to January 1, 2006 and apply the provisions of this bill to new agreements that are entered into after that date. We would accept a provision that would require any existing agreement to be reviewed after a five year period of time following the same process outlined in the draft.

We are aware that the coroners have a concern about the release of tissues from decedent's that are in their custody. I expect you will hear from their lobbyist today on that issue.

We would not be able to support the bill unless the grandfather provision is included. I think Debora makes a valid point about possible impairment of contracts.

Bill

From: Becher, Scott [mailto:Scott.Becher@legis.state.wi.us]
Sent: Friday, December 30, 2005 2:56 PM
To: aoconnor@murphydesmond.com; pcc@quarles.com; la.maroney@hosp.wisc.edu; wadiummm@co.outagamie.wi.us; Bill McCoshen; mcintosh@broydrick.com; mmettner@broydrick.com; Sweet, Richard; LLeitch@wha.org; jbloch@wha.org; kbablitch@milwcnty.com; mmcnally@fmih.edu; Robert J. Jambois (Business Fax); Jambois, Robert - DOT
Subject: FW: Draft review: LRB 05s0425/P1 Topic: Anatomical gifts and powers and duties of coroners and medical examiners

Enclosed is a copy of the amendment that Debora Kennedy drafted regarding Assembly Bill 830. I am expecting an answer from all of you no later than January 4th at 12 PM, if you have changes to be made. The Assembly Health Committee has scheduled an Executive Session on January 10th, Assembly Bill 830 is going to be on the schedule if I can get your help. I would like to find out problems earlier than later.

I think that you we are very close to making law.

01/04/2006

*No; K
could not
be
changed*

Scott Becher
Rep. Steve Wieckert
(608) 266-3070

From: Northrop, Lori
Sent: Friday, December 30, 2005 1:43 PM
To: Rep.Wieckert
Subject: Draft review: LRB 05s0425/P1 Topic: Anatomical gifts and powers and duties of coroners and medical examiners

Following is the PDF version of draft LRB 05s0425/P1 and drafter's note.

Kennedy, Debora

From: Christianson, Peter C. [PCC@quarles.com]
Sent: Wednesday, January 04, 2006 2:12 PM
To: Kennedy, Debora
Cc: Becher, Scott
Subject: I have not forgotten everything that I learned in law school!

If the contract take longer than a year to perform, it must be in writing, per Wis. Stats. s. 241.02!

241.02 Agreements, what must be written.

(1) In the following case every agreement shall be void unless such agreement or some note or memorandum thereof, expressing the consideration, be in writing and subscribed by the party charged therewith:

(a) Every agreement that by its terms is not to be performed within one year from the making thereof.

(b) Every special promise to answer for the debt, default or miscarriage of another person.

(c) Every agreement, promise or undertaking made upon consideration of marriage, except mutual promises to marry.

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Kennedy, Debora

From: Dalessandro Anthony M [am.dalessandro@hosp.wisc.edu]
Sent: Wednesday, January 04, 2006 12:25 PM
To: Becher, Scott; Kennedy, Debora; pcc@quarles.com; Maroney Lisa A.
Subject: RE: Draft review: LRB 05s0425/P1 Topic: Anatomical gifts and powers and duties of coroners and medical examiners

Scott, Overall I think this is fine but wouldn't you want to review any existing agreement at the conclusion of its current term rather than giving all current agreements a 5 year term before review? Tony

From: Becher, Scott [mailto:Scott.Becher@legis.state.wi.us]
Sent: Wed 1/4/2006 11:12 AM
To: Kennedy, Debora; pcc@quarles.com; Maroney Lisa A.; tony@tx.surgery.wisc.edu
Subject: FW: Draft review: LRB 05s0425/P1 Topic: Anatomical gifts and powers and duties of coroners and medical examiners

From: Bill McCoshen [mailto:bill.mccoshen@capitolconsultants.net]
Sent: Wednesday, January 04, 2006 10:30 AM
To: Becher, Scott
Cc: ssabo@atsfoundation.org; lshinstine@charter.net; rturner@lifeshareok.org; wem@dewittross.com
Subject: RE: Draft review: LRB 05s0425/P1 Topic: Anatomical gifts and powers and duties of coroners and medical examiners

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Bill

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Sent: Friday, December 30, 2005 2:56 PM
To: aoconnor@murphydesmond.com; pcc@quarles.com; la.maroney@hosp.wisc.edu;
wadiummm@co.outagamie.wi.us; Bill McCoshen; mcintosh@broydrick.com;
mnettner@broydrick.com; Sweet, Richard; LLeitch@wha.org; jbloch@wha.org;
kbablitch@milwcnty.com; mmmcnally@fmlh.edu; Robert J. Jambois (Business Fax); Jambois,
Robert - DOT
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I think that you we are very close to making law.

Scott Becher

Rep. Steve Wieckert

(608) 266-3070

From: Northrop, Lori
Sent: Friday, December 30, 2005 1:43 PM
To: Rep.Wieckert
Subject: Draft review: LRB 05s0425/P1 Topic: Anatomical gifts and powers and duties of
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Sent: Wednesday, January 04, 2006 1:03 PM
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Subject: FW: Draft review: LRB 05s0425/P1 Topic: Anatomical gifts and powers and duties of coroners and medical examiners

-----Original Message-----

From: Dalessandro Anthony M [mailto:am.dalessandro@hosp.wisc.edu]
Sent: Wednesday, January 04, 2006 12:25 PM
To: Becher, Scott; Kennedy, Debora; pcc@quarles.com; Maroney Lisa A.
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Subject: FW: Draft review: LRB 05s0425/P1 Topic: Anatomical gifts and powers and duties of coroners and medical examiners

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I think that you we are very close to making law.

Scott Becher

Rep. Steve Wieckert

(608) 266-3070

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Subject: Draft review: LRB 05s0425/P1 Topic: Anatomical gifts and powers and duties of coroners and medical examiners

Following is the PDF version of draft LRB 05s0425/P1 and drafter's note.

Dick Sweet - Form issue ✓

Kennedy, Debora

From: Becher, Scott
Sent: Wednesday, January 04, 2006 11:59 AM
To: Kennedy, Debora
Subject: FW: Draft review: LRB 05s0425/P1 Topic: Anatomical gifts and powers and duties of coroners and medical examiners

From: Sweet, Richard
Sent: Wednesday, January 04, 2006 10:18 AM
To: Becher, Scott
Subject: RE: Draft review: LRB 05s0425/P1 Topic: Anatomical gifts and powers and duties of coroners and medical examiners

Scott,

A few comments on LRBs0425/P1:

- ✓ 1. A portion of the LRB analysis should be revised. There are a couple of sentences about half-way down on page 2 that discuss physicians **or technicians** removing organs. I think that technicians can remove tissue or bones, but not organs. Same issue on page 5, line 21. } see my change
- ✓ 2. It might be a little repetitive, but I think the coroners would be more comfortable if "the coroner, medical examiner, or designee" were inserted on page 5, line 9, before "may". If it gets too repetitive, similar language could be removed on line 8; but I think the coroners/MEs will want to see it on line 9.
- ✓ 3. I wonder if the paragraph at the bottom of page 5 can be combined with the paragraph at the top of page 6. (This is a question you may want to run by the UW people.) Paragraph (cm) requires completion of a state-designed form on organ donations. Paragraph (d) requires (upon request) completion of a report on cardiovascular tissue. In combining the 2, it might be good to keep the language "detailing the condition . . . and its relationship to the cause of death" in describing what the state-designed form is used for.
- ✓ 4. Page 7, line 2 allows the coroner/ME's tissue bank to approach a family member to request an anatomical gift of all or a part of the decedent's body. Since a tissue bank is doing this, it should probably be limited to just requests for tissue. Same change in the analysis on page 3.
- ✓ 5. On page 7, line 19, "all of" should be inserted after "by". Also, I think the consensus of the group was that passive review action had to be completed with 60 days. As drafted (and as Joint Finance passive review works), a request to review could extend this indefinitely. I think what they wanted was that there not be a **request** for review by the county board, but that the county board would either have to approve it or disapprove it within 60 days; if they

01/04/2006

do nothing within the 60 days, it's approved.

Dick Sweet

Richard Sweet
Senior Staff Attorney
Wisconsin Legislative Council
(608)266-2982
richard.sweet@legis.state.wi.us

From: Becher, Scott
Sent: Friday, December 30, 2005 2:56 PM
To: 'M. Alice O'Connor (aoconnor@murphydesmond.com)'; Peter C. Christianson (pcc@quarles.com); Lisa Maroney (la.maroney@hosp.wisc.edu); Mark Wadium (Mark Wadium [wadiummm@co.outagamie.wi.us]); William J. McCoshen (bill.mccoshen@capitolconsultants.net); Forbes McIntosh (mcintosh@broydrick.com); Michelle Mettner (mmettner@broydrick.com); Sweet, Richard; Laura Leitch (LLeitch@wha.org); Jodi Bloch (jbloch@wha.org); Kelly Bablitch (kbablitch@milwcnty.com); Maureen McNally (mmcnally@fmlh.edu); Robert J. Jambois (Business Fax); Jambois, Robert - DOT
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Following is the PDF version of draft LRB 05s0425/P1 and drafter's note.

✓
ok

Kennedy, Debora

From: Becher, Scott
Sent: Wednesday, January 04, 2006 1:02 PM
To: Kennedy, Debora
Subject: FW: One other point

-----Original Message-----

From: Dalessandro Anthony M [mailto:am.dalessandro@hosp.wisc.edu]
Sent: Wednesday, January 04, 2006 12:28 PM
To: Becher, Scott
Subject: RE: One other point

Scott, I agree with this point. Tony

From: Becher, Scott [mailto:Scott.Becher@legis.state.wi.us]
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Scott,

One more issue. In point 3 of Debora's memo it should be clear that there won't be a separate agreement for each referral.

Thanks.

Bill



Kennedy, Debora

From: Becher, Scott
Sent: Wednesday, January 04, 2006 11:15 AM
To: Peter C. Christianson (pcc@quarles.com); Lisa Maroney (la.maroney@hosp.wisc.edu); Anthony M. D'Alessandro (tony@tx.surgery.wisc.edu); Kennedy, Debora
Subject: FW: One other point

From: Bill McCoshen [mailto:bill.mccoshen@capitolconsultants.net]
Sent: Wednesday, January 04, 2006 10:40 AM
To: Becher, Scott
Cc: ssabo@atsfoundation.org; lshinstine@charter.net; rturner@lifeshareok.org; wem@dewittross.com
Subject: One other point

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Thanks.

Bill

*Jentzen - Forensic pathologist denial issue***Kennedy, Debora**

From: Becher, Scott
Sent: Wednesday, January 04, 2006 5:44 PM
To: 'Peter C. Christianson (pcc@quarles.com)'; Kennedy, Debora
Subject: FW: AB 830

From: JJentzen@milwcnty.com [mailto:JJentzen@milwcnty.com]
Sent: Wednesday, January 04, 2006 5:42 PM
To: Becher, Scott
Subject: AB 830

Dear Mr. Becher:

my concern on the legislation is on page 5 line 10. It should read:

I denial of removal is a possibility, the coroner or medical examiner shall consult with a board-certified forensic pathologist to determine the necessity of the organ in the determination of the cause and manner of death. The organ procurement organization may consult the forensic pathologist in conjunction with the coroner or medical examiner.

Note: A denial shall be defined as denial of all organs and tissues, not simple a single organ.

thanks for you help,

jeff jentzen

01/05/2006

Kennedy, Debora

From: Becher, Scott
Sent: Thursday, January 05, 2006 9:32 AM
To: Kennedy, Debora
Subject: FW: Response to Jeff Jentzen suggestion

-----Original Message-----

From: Christianson, Peter C. [mailto:PCC@quarles.com]
Sent: Thursday, January 05, 2006 8:44 AM
To: Becher, Scott
Cc: Dalessandro Anthony M; Maroney Lisa A.
Subject: Response to Jeff Jentzen suggestion

Pasted below is the text of an e-mail sent by Jeffrey Jentzen, MD. We do not want to see this proposal incorporated into the substitute amendment. Here are the reasons:

1. This language would require a coroner or medical examiner who is considering blocking a donation to consult with a forensic pathologist. This may place an undue burden on the coroner or medical examiner.
2. If every denial becomes a denial of all organs and tissues and not simply a denial of the implicated organ or tissue, many potential donations will be denied for no good reason.

Dear Mr. Becher:

my concern on the legislation is on page 5 line 10. It should read:

If denial of removal is a possibility, the coroner or medical examiner shall consult with a board-certified forensic pathologist to determine the necessity of the organ in the determination of the cause and manner of death. The organ procurement organization may consult the forensic pathologist in conjunction with the coroner or medical examiner.

Note: A denial shall be defined as denial of all organs and tissues, not simple a single organ.

thanks for you help,

jeff jentzen

This electronic mail transmission and any attachments are confidential and may be privileged. They should be read or retained only by the intended recipient. If you have received this transmission in error, please notify the sender immediately and delete the transmission from your system. In addition, in order to comply with Treasury Circular 230, we are required to inform you that unless we have specifically stated to the contrary in writing, any advice we provide in this email or any attachment concerning federal tax issues or submissions is not intended or written to be used, and cannot be used, to avoid federal tax penalties.

§ 482.45 Condition of participation: Organ, tissue, and eye procurement.

(a) *Standard: Organ procurement responsibilities.* The hospital must have and implement written protocols that:

(1) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose;

(2) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

(3) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its options to donate organs, tissues, or eyes or to decline to donate. The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

(4) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

(5) Ensure that the hospital works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary test-

ing and placement of potential donated organs, tissues, and eyes take place.

(b) *Standard: Organ transplantation responsibilities.* (1) A hospital in which organ transplants are performed must be a member of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274) and abide by its rules. The term "rules of the OPTN" means those rules provided for in regulations issued by the Secretary in accordance with section 372 of the PHS Act which are enforceable under 42 CFR 121.10. No hospital is considered to be out of compliance with section 1138(a)(1)(B) of the Act, or with the requirements of this paragraph, unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing.

(2) For purposes of these standards, the term "organ" means a human kidney, liver, heart, lung, or pancreas.

(3) If a hospital performs any type of transplants, it must provide organ-transplant-related data, as requested by the OPTN, the Scientific Registry, and the OPOs. The hospital must also provide such data directly to the Department when requested by the Secretary.

[63 FR 33875, June 22, 1998]

Subpart D—Optional Hospital Services

§ 482.51 Condition of participation: Surgical services.

If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

(a) *Standard: Organization and staffing.* The organization of the surgical services must be appropriate to the scope of the services offered.

(1) The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.

Health Law Alert

HALL,
RENDER, KILLIAN,
HEATH & LYMAN

Hospital Responsibilities for Tissue Donation

July 6, 2005

Todd J. Selby, Esq.
Hall, Render, Killian, Heath & Lyman, P.S.C.

Executive Summary

On June 27, 2005, the Centers for Medicare & Medicaid Services ("CMS") issued correspondence surrounding tissue donation in Medical Examiner ("ME") and/or Coroner jurisdictional cases. The correspondence involved an inquiry from an ME concerning whether an ME could directly notify a tissue recovery agency. The ME would, in turn, request hospitals, in ME/Coroner cases, to contact the ME prior to contacting the Federally Designated Organ procurement Organization ("OPO") in tissue donation cases. CMS stated that under no circumstances could a hospital allow the ME to make direct contact with the tissue recovery agency.

Detailed Analysis

On June 27, 2005, CMS issued correspondence to an ME concerning the ME's ability to directly contact a tissue recovery agency with which the ME had a contractual relationship. CMS stated that under no circumstances could the ME make a direct referral to the tissue recovery agency as this would be in violation of Federal regulations governing organ, tissue, and eye procurement found at 42 CFR 482.45. CMS notified the ME that pursuant to 482.45(a)(1) and (a)(2), it is the hospital's responsibility to have an agreement with the designated OPO. Further, it is the hospital's responsibility to notify in a timely manner the OPO, or third party designated by the OPO, of individuals whose deaths are imminent or who have died in the hospital. Additionally, it is a hospital's responsibility and not that of the ME to have an agreement with at least one (1) tissue bank and at least one

Does
the
make
157.06
(4r)(b)
a problem?

(1) eye bank for the retrieval, processing, preservation, storage and distribution of tissue and eyes as may be appropriate to ensure that all potential donors are identified. It is unnecessary for the hospital to have a separate agreement with the tissue bank if the OPO is utilized for tissue recovery. CMS stated that to require a hospital to contact an ME or Coroner prior to notifying the OPO would circumvent the intent of the regulations which is to allow the hospital to make the direct referral to the OPO and not to the ME or Coroner.

In summary, it is the hospital's responsibility to: (1) notify the OPO in a timely manner of a patient's imminent death or that a patient has died in the hospital; (2) have a contract with the OPO; (3) have a contract with a tissue recovery agency in the event that the hospital does not contract with the OPO for tissue recovery; and, (4) under no circumstances should a hospital allow the ME or Coroner to make a direct referral to the OPO or a tissue recovery agency as this would be in violation of the Federal regulations governing organ, tissue and eye procurement.

Should you have any questions regarding the information above, please do not hesitate to contact your local counsel or Todd J. Selby at 317/977-1440 Hall, Render, Killian, Heath & Lyman, P.S.C.

About Hall Render:

Hall, Render, Killian, Heath & Lyman is a full service law firm with offices in Indiana, Kentucky, Michigan and Wisconsin. Since the firm was founded by William S. Hall in 1967, Hall Render has focused its practice primarily in the area of health law and is now recognized as one of the nation's preeminent health law firms.

Hall Render attorneys today serve the legal needs of all types and sizes of healthcare providers, from multi-billion dollar national health systems to sole practitioner physicians. In addition to its healthcare clients, the firm's attorneys also serve the legal needs of a wide variety of other businesses and individuals. Hall Render invites you to learn more about its services and professionals on its web site at www.hallrender.com.

This publication is intended for general information purposes only and does not and is not intended to constitute legal advice. The reader must consult with legal counsel to determine how laws or decisions discussed herein apply to the reader's specific circumstances.

1/5/06

For Scott Becker - mtg.

Major problems:

1. Are the agreements contracts or not?

Guia Reese: no

Bill McCosken: yes

2. Problem with 156.07(4r) ^{(a) 4 +} (b) (intro.)

Laura Heitch's version - doesn't work

Pete Christianson's version

Dick Sweet's proposal

3. Forensic pathologist - (denial of removal)
Jeff Jentzen's proposal

4. Combining forms (157.06 (4m) (cm) + (d)).



Stephen R. Miller
Chief

State of Wisconsin

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January 5, 2006

MEMORANDUM

To: Representative Steve Wieckert

From: Debora A. Kennedy

Subject: Referral to tissue banks

The following, with commentary, are the several versions proposed for s. 157.06 (4r) (a) 4. and (b) (intro.) for the substitute amendment to 2005 Assembly Bill 830:

1. The version in s0425/P1:

157.06 (4r) (a) 4. If subsds. 2. and 3. apply (*i.e., decedent is in custody of C or ME, death occurred in hospital, hospital's tissue bank has refused, tissue bank has so notified C or ME, C or ME has notified its tissue bank, and that tissue bank has agreed to accept and has requested family to donate*), the hospital in which the decedent's death occurred shall do one of the following:

a. Enter into a written agreement with the tissue bank specified in subd. 3. that authorizes the tissue bank to remove the decedent's tissue in the hospital.

b. Release the decedent to the tissue bank specified in subd. 3. for removal of the decedent's tissue in a place other than in the hospital.

(b) If a decedent is within the custody of a coroner or medical examiner, the death occurred outside a hospital, and the coroner or medical examiner refers the decedent as a potential tissue donor, any such referral shall be made under the following conditions:

2. The version proposed in Pete Christianson's January 3 e-mail:

157.06 (4r) (a) 4. If subsds. 2. and 3. apply (*see italics above in version 1.*), the coroner or medical examiner may remove the body from the hospital in which the body is located.

(b) If a decedent is within the custody of a coroner or medical examiner, the death occurred outside a hospital or the decedent was removed from a hospital, and the coroner or medical examiner refers the decedent as a potential tissue donor, any such referral shall be made under the following conditions:

3. The version proposed in Laura Leitch's January 4 e-mail:

157.06 (4r) (b) If the decedent is within the custody of the coroner or the medical examiner, under the circumstances described in par. (a) 4. or the death occurred outside a hospital, and the coroner or medical examiner refers the decedent as a potential tissue donor, any such referral shall be made under the following conditions:

Note: Laura's e-mail indicates that it was thought that this language makes it clearer that par. (b) would only apply when the death occurred outside a hospital. This is incorrect, however, since "under the circumstances described in par. (a) 4." refers to a death within a hospital, and "or" confirms that both the in-hospital and the outside-the-hospital circumstances are described.

4. A version worked on by Debora Kennedy and Dick Sweet:

157.06 (4r) (a) 4. If subds. 2. and 3. apply (see italics above in version 1.), and if the anatomical gift is made, the hospital shall release the decedent to the tissue bank specified in subd. 3. for removal of the decedent's tissue.

(b) If a decedent is within the custody of a coroner or medical examiner, the death occurred outside a hospital, and the coroner or medical examiner refers the decedent as a potential tissue donor, any such referral shall be made under the following conditions:

when

a cor me communicates to the hospital that

the decedent or was transferred to a cor me from a hosp under subd. (a) 4.

consent is given for an

transfer the decedent to the cor or me

Kennedy, Debora

From: Becher, Scott
Sent: Thursday, January 05, 2006 12:51 PM
To: Sweet, Richard; 'Peter C. Christianson (pcc@quarles.com)'; Kennedy, Debora
Subject: FW: WCMEA comments
Attachments: letter to wieckert 1-4-05.pdf

From: Alice O'Connor [mailto:AConnor@murphydesmond.com]
Sent: Thursday, January 05, 2006 12:23 PM
To: Becher, Scott
Subject: WCMEA comments

Hi <<letter to wieckert 1-4-05.pdf>> Scott,

Will see you at 1:30 and will be bringing a copy of this letter with.

Alice M. O'Connor

Director of Government Relations

Murphy Desmond S.C.

2 E. Mifflin Street, Suite 800

P.O. Box 2038

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01/05/2006



WISCONSIN CORONERS & MEDICAL EXAMINERS ASSOCIATION

January 4, 2005

Representative Steve Wieckert
P.O. Box 8953
Madison, WI 53708

Dear Representative Wieckert:

The purpose of this letter is to formally respond on behalf of the Wisconsin Coroners and Medical Examiners Association to LRB 0425/1dn, drafted as a substitute amendment to AB 830. Our responses and suggestions also address concerns raised in the December 30, 2005 drafters note from Debra Kennedy to you. A number of changes to the bill are a significant improvement and we applaud your leadership in this endeavor. What follows is further recommendations to clarify statutory intent of what we believe was agreed to in discussions with all the interested parties.

Custody Concern

Current law provides authority for coroners and medical examiners to retain jurisdiction and custody of a decedent, even to the point of disinterment and re-examination if necessary. Therefore, concerns about returning custody to the coroner or medical examiner aren't relevant. Hospitals do not need to be concerned. The bill language in several places points out that coroners and medical examiners are not relinquishing jurisdiction or custody of the decedent, but simply releasing "the body part(s) that are subject to donation".

Examples stated in substitute language:

Page 3, line 5 correctly references "of a part of a human body".

Page 4, line 2 states "removal of a part from, a decedent specified in paragraph (ag) within that official's custody. (Note: official's custody is a coroner or medical examiner)

Page 4, line 6 references "removal of a part of a human body..."

Page 4, lines 8 and 9 references "the part of the body requested".

Page 4, line 14 references the custody of the decedent being "within the jurisdiction of a coroner or medical examiner under ch. 979.

Page 4, line 23 references the "coroner or medical examiner with jurisdiction over the decedent".

The bill correctly states that when an organ or tissue is removed for donation, the body part is all that is released from custody of the coroner or medical examiner. Therefore, the concerns raised by WHA are not relevant in those situations where a tissue bank, who has a contractual arrangement with a hospital chooses to decline a potential donation and the coroner or medical examiner is contacted to see if a willing donation might be acceptable to one of the other tissue services working from a written agreement with a specific county coroner or medical examiner.

It is important to distinguish between "contracts" and "written agreements" because the drafting note appears to combine both terms. They should not be used interchangeably. Coroners and medical examiners under language proposed in this bill enter into written agreements, if a variety of criteria are met, they are not binding contracts.

The following changes in the LRB Analysis are suggested for consistency with the language proposed in the bill:

- On page 2, lines 19, 20 & 21 should reflect the language suggested in **Section 6. , Page 5, Lines 5-15.**
- On page 2, third line from the bottom, ~~the release~~ should be changed to the tissue donation.
- On page 2, the bottom two lines should have language suggested in **Section 7., Page 6, Line 18.**
- On page 3, on the first line, ~~the release~~ should be changed to tissue donation.
- On page 3, on line 7, ~~the tissue bank~~ should be changed to then coroner or medical examiner.

The following changes are a consolidation of suggestions from the WCMEA, WHA and OPO that will enhance AB 830.

D-Note ✓ **Page 3 Line 10**

**OR MEDICAL EXAMINER;
ANATOMICAL GIFT DONORS**

DECEDENT NOT A DONOR POTENTIAL

Rationale: This section does address potential anatomical gift donors

fixed
disagree

Page 4 Line 11

157.06 (4m) AUTHORIZATION BY CORONER OR MEDICAL EXAMINER;
DECEDENT A POTENTIAL ORGAN DONOR

AND TISSUE,

Rationale: This section is specific to potential organ donors

Page 4 Line 12

DONOR. (a) Subject to par. (b) for a decedent potential donor who meets the criteria for a

This doesn't work

disagree

Rationale: At this point the term decedent is premature - No

Page 4 Line 18 - 24

1. Immediately after the ~~administrator~~ of the hospital in which the donor or potential donor is located, ~~or a representative designated by the administrator~~ contacts the organ procurement organization designated for the region of which the hospital is a part concerning the potential donation, the organ procurement organization shall, by oral conversation, provide notice of the intended removal referral of the potential donor to the coroner or medical examiner or his or her designee and shall provide notice to the district attorney or his or her designee.

disagree

fixed

Rationale: There is no need to identify with specificity which hospital officials have the power to contact the OPO

Page 5 Line 5 - 15

Section 6 157.06 (4m) (b) If, in the judgment of the coroner, medical examiner, or designee specified in par. (a) the vascularized organ may be necessary in determining the cause of death, ~~if the coroner, medical examiner, or designee may order a biopsy of the vascularized organ or, if the coroner, medical examiner, or designee is present during the physician's scheduled removal, they may deny removal.~~ If denial of removal is a possibility, the organ procurement organization may consult with a the forensic pathologist designated by the coroner, medical examiner, or designee, if available, as to the pathologist's opinion concerning the necessity of the organ in determining the cause of death.

not grammatical

Rationale: A coroner or medical examiner will usually make a decision to decline a donation prior to physician's scheduled removal. The OPO should be consulting the forensic pathologist that will eventually conduct the forensic medical examination at autopsy. That person is designated by the coroner or medical examiner

[Handwritten signature]

Page 5 Line 21

Delete Subsection (cm)

Rationale: The provisions of this subsection are now included in subsection (e)

Page 6 Line 6

Section 6 157.06 (4m) (e) If a coroner or medical examiner or his or her designee releases and permits the removal of a part under this subsection, ~~the recovering agency shall maintain a permanent record of the name of the decedent, the name of the person, if any, who made an anatomical gift under sub. (3), the date and purpose of the document of gift, the part of the body removed, and the name of the person whom the part was released. The recovering agency shall make the record under this paragraph available, upon request, to the coroner or medical examiner.~~ Section, the physician or technician who removes an organ or tissue shall complete a form, as specified in sub. (9m), and transmit the completed form to the coroner or medical examiner with jurisdiction over the decedent.

Rationale: The purpose of this section is to assure that donations recovered from a body under the jurisdiction of the coroner or medical examiner are properly documented on a uniform reporting form and communicated.

DAK
check

(cm)
+
(e)
continued

Page 6 Line 14

157.06 (4r) AUTHORIZAZION BY CORONER OR MEDICAL EXAMINER; POTENTIAL TISSUE DONEE DONOR. (a) 1. If

Rationale: This section is specific to potential tissue donors

diagnose

Page 6 Line 16

✓ occurred in a hospital, any release by ~~the hospital~~ of the decedent as a potential tissue

Rationale: The hospital does not release the potential tissue donation in cases where the coroner or medical examiner maintains jurisdiction and custody of the decedent.

Page 6 Line 19

✓
ok release tissue donation, the tissue bank shall so notify the coroner or medical examiner.

Rationale: This change explains what the tissue service is actually unwilling to receive

Page 6 Line 25

ok willing to receive the ~~release~~ tissue donation, shall contact an available individual , under the priority

Rationale: Same as previous statement

Page 7 Lines 5 - 6

X a. Enter into a written facility use agreement with the tissue bank specified in subd. 3 that authorizes the tissue bank to remove the decedent's tissue in the hospital.

Rationale: This clarifies that the hospital may want to have an agreement with an additional tissue service, solely for the use of the hospital facility for tissue recovery purposes only

Transfer

Page 7 Line 7 - 8

b. Release the decedent to the ~~tissue bank specified in subd. 3~~ coroner or medical examiner for removal of the decedent's tissue in a place other than the hospital.

Rationale: This change makes it clear that the coroner or medical examiner is still exercising jurisdiction and custody of the decedent

No Duplies has given up & is ~~at~~ bank

Page 7 Line 9 - 12

(b) If When a decedent is within the custody of a coroner or medical examiner, the death occurred outside a hospital, or if the decedent was removed from the hospital, and the coroner or medical examiner refers the decedent as a potential tissue donor, any such referral shall be made under the following conditions:

Rationale: If the decedent was removed from the hospital, then tissue donations are handled in the same manner as other out-of-hospital tissue donations referred by the coroner or medical examiner

Page 8 Line 6

4. Written agreements in effect at the time of this Act shall remain in effect according to terms of those respective agreements.

Rationale: Many coroners and medical examiners have active written agreements that should be honored as negotiated

See 1/06/06 agreement

Page 8 Line 17

Section 9. 157.06 (9m) ORGAN AND TISSUE REMOVAL FORM; RULES. The department of health and family services shall promulgate rules prescribing an organ removal form for use under sub. (4m) ~~(em)~~ (e).

Rationale: Standardized reporting of tissue donations should be included in the uniform reporting forms

fix C/1/5/06

Page 8 Lines 22, 23, 24 & 25

Delete **Section 12**, entirely

Rationale: There appears to be unanimous agreement that this section is not necessary

Page 9 Line 2

ORGAN AND TISSUE REMOVAL FORM: ADVISORY COMMITTEE: EMERGENCY RULES.

Rationale: Same as section 9 above

Page 9 Line 3 - 8

(a) The Secretary of health and family services shall appoint an advisory committee under section 15.04 (1) (c) of the statutes that shall include coroners, medical examiners, forensic pathologists, organ and tissue procurement organization personnel, and district attorneys, to assist the department of health and family services in prescribing, by rule, an

organ and tissue removal forms for use under section 157.06 (4m)(cm)
(e) of the statutes, as created by this act.

Rationale: A committee convened to develop forms should include representation from parties that will generate and utilize the forms

We believe that if the above changes are incorporated into the substitute amendment, the Wisconsin Coroners and Medical Examiners can wholeheartedly support this legislation. We would like to see the recommended changes in a revised draft before we give our official, final support. On behalf of the WCMEA, we thank you, Rep. Wieckert, for your yeoman efforts to bring good legislation forward. We will look forward to hearing from you.

Yours truly,

Traci England

Traci England
WCMEA President
(715) 277-4972
redculad@networth.net

John E. Stanley

John Stanley
WCMEA Leg. Chair
(608) 284-6011
stanley@co.dane.wi.us

1/5/06 Mtg.

Tony D'Alessandro, Scott Becker, John Stanley,
Alicia O'Connor, Lisa Maroney, Laura Leitch,
Dick Sweet, Bill McCosken, Michelle Mitter,
Jody Bloch, Forbes McEntosh

~~Existing agreements & K's~~

- ✓ 1. ~~Group forensic pathologist~~ p. 5, ll 5-15
Presence of c or me ^{or designee} at time of renewal

Unresolved

2. Agreements v. contracts

- ✓ (a) Group agreed agreements are not K's
(b) When do requests apply?

157.06(4v)(a) 4.

- ✓ 3. If a c or me ~~confirms that subject~~
communicates to the hoop that
subs. 2 + 3 apply, and that ~~the~~
~~noat gift is made~~
if consent is given for an anat gift

Group: OK as proposed by DS + DAK

- ✓ p. 7, l. 9 - change "If" to "when"

2. (again)

When do agreements apply? - ~~2/1/06~~

x Group: year + 3mo from eff date

undecided: To be decided 1/5/06 ~~10:00~~ am. leg Council
11:00

A. Focus

~~Separate~~

~~2 focus~~

p. 5+6

2 focus - organs

other tissues, other than cardiac
(See Alice O'Connor's memo)

(d) stays as is

↓ phys who removes
fills out +
transmits to

time banks forward to come

come

✓ 1. (again) p 5, l. 5-15 - look at p. 2 DAK memo
of 1/5/06

✓ 5. Forensic pathologist issue raised by Jeff Jentzen:
Group: do not include

(denial of all organs +
tissues)

1/6/06 Mds: Scott Becker, Forbes Mc Intosh, Bill Mc Coshen,
Michelle Mettenen, etc.

① Add "triose bank employee" to par. (e) + (f)

② Agreements - when existing agreements are to
be affected?

(a) 1 yr. after enactment

(b) 12/31/07

(c) 15 mo after enactment 10/1/07

Agreed:

All agreements must conform to
bill by 10/1/07.