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HIPAA Organized Health Care Arrangements

[Ver 3.0]

Rules and Resources

Wednesday, January 7, 2004
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What is an "Organized Health Care Arrangement"?

§ 160.103 Definitions.[1] Except as otherwise provided, the following definitions apply to this subchapter:

* * *

Organized health care arrangement means:

(1) A clinically integrated care setting in which individuals typically receive health care from more than one health care provider;

(2) An organized system of health care in which more than one covered entity participates, and in which the participating covered entities:

(i) Hold themselves out to the public as participating in a joint arrangement; and

(ii) Participate in joint activities that include at least one of the following:

(A) Utilization review, in which health care decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf;

(B) Quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; or

(C) Payment activities, if the financial risk for delivering health care is shared, in part or in whole, by participating covered entities through the joint arrangement and if protected health information created or received by a covered entity is reviewed by other participating covered entities or by a third party on their behalf for the purpose of administering the sharing of financial risk.

(3) A group health plan and a health insurance issuer or HMO with respect to such group health plan, but only with respect to protected health information created or received by such health insurance issuer or HMO that relates to individuals who are or who have been participants or beneficiaries in such group health plan;[2]

(4) A group health plan and one or more other group health plans each of which are maintained by the same plan sponsor;[3] or

(5) The group health plans described in paragraph (4) of this definition and health insurance issuers or HMOs with respect to such group health plans, but only with respect to protected health information created

[1] Security Rule changes to this section discussed generally in the Preamble, 68 FR 8334, 8339.

[2] "The Department clarifies that, if more than summary health information is needed for this purpose, paragraphs (3), (4), and (5) of the definition of "organized health care arrangement" may permit the disclosure. These provisions define the arrangements between group health plans and their health insurance issuers or HMOs as OHCAs, which are permitted to share information for each other's health care operations. Such disclosures also may be made to a broker or agent that is a business associate of the health plan. The Department clarifies that the OHCA provisions also permit the sharing of protected health information between such entities even when they no longer have a current relationship, that is, when a group health plan needs protected health information from a former issuer.." Preamble to final revisions, 67 FR 53217-18

[3] *Ibid.*

or received by such health insurance issuers or HMOs that relates to individuals who are or have been participants or beneficiaries in any of such group health plans.[4]

* * *

Sec. 164.105 Organizational requirements.

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(b) (1) *Standard: Affiliated covered entities*.[5] Legally separate covered entities that are affiliated may designate themselves as a single covered entity for purposes of subparts C and E of this part.

(1) Implementation specifications:

(i) Requirements for designation of an affiliated covered entity.

(A) Legally separate covered entities may designate themselves (including any health care component of such covered entity) as a single affiliated covered entity, for purposes of subparts C and E of this part, if all of the covered entities designated are under common ownership or control.

(B) The designation of an affiliated covered entity must be documented and the documentation maintained as required by paragraph (c) of this section.

(ii) Safeguard requirements. An affiliated covered entity must ensure that:

(A) The affiliated covered entity's creation, receipt, maintenance, or transmission of electronic protected health information complies with the applicable requirements of subpart C of this part;

(B) The affiliated covered entity's use and disclosure of protected health information comply with the applicable requirements of subpart E of this part; and

(C) If the affiliated covered entity combines the functions of a health plan, health care provider, or health care clearinghouse, the affiliated covered entity complies with Sec. 164.308(a)(4)(ii)(A) and Sec. 164.504(g), as applicable.

Preamble to final rule
65 FR 82494 – 5.

Organized Health Care Arrangement

This term was not used in the proposed rule. We define the term in order to describe certain arrangements in which participants need to share protected health information about their patients to manage and benefit the

[4] *Ibid.*
[5] Replaces 45 CFR 164.504(d).

common enterprise. To allow uses and disclosures of protected health information for these arrangements, we also add language to the definition of ''health care operations.'' See discussion of that term above.

We include five arrangements within the definition of ***organized health care arrangement***. The arrangements involve clinical or operational integration among legally separate covered entities in which it is often necessary to share protected health information for the joint management and operations of the arrangement. They may range in legal structure, but a key component of these arrangements is that individuals who obtain services from them have an expectation that these arrangements are integrated and that they jointly manage their operations. We include within the definition a clinically integrated care setting in which individuals typically receive health care from more than one health care provider. Perhaps the most common example of this type of ***organized health care arrangement*** is the hospital setting, where a hospital and a physician with staff privileges at the hospital together provide treatment to the individual. Participants in such clinically integrated settings need to be able to share health information freely not only for treatment purposes, but also to improve their joint operations. For example, any physician with staff privileges at a hospital must be able to participate in the hospital's morbidity and mortality reviews, even when the particular physician's patients are not being discussed. Nurses and other hospital personnel must also be able to participate. These activities benefit the common enterprise, even when the benefits to a particular participant are not evident. While protected health information may be freely shared among providers for treatment purposes under other provisions of this rule, some of these joint activities also support the health care operations of one or more participants in the joint arrangement. Thus, special rules are needed to ensure that this rule does not interfere with legitimate information sharing among the participants in these arrangements.

We also include within the definition an organized system of health care in which more than one covered entity participates, and in which the participating covered entities hold themselves out to the public as participating in a joint arrangement, and in which the joint activities of the participating covered entities include at least one of the following: utilization review, in which health care decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf; quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; or payment activities, if the financial risk for delivering health care is shared in whole or in part by participating covered entities through the joint arrangement and if protected health information created or received by a covered entity is reviewed by other participating covered entities or by a third party on their behalf for the purpose of administering the sharing of financial risk. A common example of this type of ***organized health care arrangement*** is an independent practice association formed by a large number of physicians. They may advertise themselves as a common enterprise (*e.g.,* Acme IPA), whether or not they are under common ownership or control, whether or not they practice together in an integrated clinical setting, and whether or not they share financial risk.

If such a group engages jointly in one or more of the listed activities, the participating covered entities will need to share protected health information to undertake such activities and to improve their joint operations. In this example, the physician participants in the IPA may share financial risk through common withhold pools with health plans or similar arrangements. The IPA participants who manage the financial arrangements need protected health information about all the participants' patients in order to manage the arrangement. (The participants may also hire a third party to manage their financial arrangements.) If the participants in the IPA engage in joint quality assurance or utilization review activities, they will need to share protected health information about their patients much as participants in an integrated clinical setting would. Many joint activities that require the sharing of protected health information benefit the common enterprise, even when the benefits to a particular participant are not evident.

We include three relationships related to group health plans as ***organized health care arrangements***. First, we include a group health plan and an issuer or HMO with respect to the group health plan within the definition, but only with respect to the protected health information of the issuer or HMO that relates to individuals who are or

have been participants or beneficiaries in the group health plan. We recognize that many group health plans are funded partially or fully through insurance, and that in some cases the group health plan and issuer or HMO need to coordinate operations to properly serve the enrollees. Second, we include a group health plan and one or more other group health plans each of which are maintained by the same plan sponsor. We recognize that in some instances plan sponsors provide health benefits through a combination of group health plans, and that they may need to coordinate the operations of such plans to better serve the participants and beneficiaries of the plans. Third, we include a combination of group health plans maintained by the same plan sponsor and the health insurance issuers and HMOs with respect to such plans, but again only with respect to the protected health information of such issuers and HMOs that relates to individuals who are or have been enrolled in such group health plans. We recognize that is some instances a plan sponsor may provide benefits through more than one group health plan, and that such plans may fund the benefits through one or more issuers or HMOs.

Again, coordinating health care operations among these entities may be necessary to serve the participants and beneficiaries in the group health plans. We note that the necessary coordination may necessarily involve the business associates of the covered entities and may involve the participation of the plan sponsor to the extent that it is providing plan administration functions and subject to the limits in § 164.504."

Do hospital medical staffs have to enter into business associate contracts with the hospital?

Question: Do physicians with hospital privileges have to enter into business associate contracts with the hospital?

Answer: No. The hospital and such physicians participate in what the HIPAA Privacy Rule defines as an organized health care arrangement (OHCA). Thus, they may use and disclose protected health information for the joint health care activities of the OHCA without entering into a business associate agreement.

Answer ID *248,* ***Date Updated*** *07/18/2003*

Joint Notice

§ 164.520 Notice of privacy practices for protected health information.[6]

(a) Standard: notice of privacy practices[7].

(1) Right to notice. Except as provided by paragraph (a)(2) or (3) of this section, an individual has a right to adequate notice[8] of the uses and disclosures of protected health information that may be made by the covered entity[9], and of the individual's rights and the covered entity's legal duties with respect to protected health information.

(2) Exception for group health plans.

(i) An individual enrolled in a group health plan has a right to notice:

(A) From the group health plan, if, and to the extent that, such an individual does not receive health benefits under the group health plan through an insurance contract with a health insurance issuer or HMO[10]; or

(B) From the health insurance issuer or HMO with respect to the group health plan though which such individuals receive their health benefits under the group health plan.

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[6] Last updated December 8, 2002.

[7] **"Practices" defined:** "In this section of the final rule, we also refer to the covered entity's privacy "practices," rather than its "policies and procedures." The purpose of this change in vocabulary is to clarify that a covered entity's "policies and procedures" is a detailed documentation of all of the entity's privacy practices as required under this rule, not just those described in the notice. For example, we require covered entities to have policies and procedures implementing the requirements for "minimum necessary" uses and disclosures of protected health information, but these policies and procedures need not be reflected in the entity's notice. Similarly, we require covered entities to have policies and procedures for assuring individuals access to protected health information about them. While such policies and procedures will need to include documentation of the designated record sets subject to access, who is authorized to determine when information will be withheld from an individual, and similar details, the notice need only explain generally that individuals have the right to inspect and copy information about them, and tell individuals how to exercise that right." Preamble, page 82548.

[8] **Multiple notices:** "[C[overed entities may want or be required to produce more than one notice in order to satisfy the notice content requirements under this rule. For example, a covered entity that conducts business in multiple states with different laws regarding the uses and disclosures that the covered entity is permitted to make without authorization may be required to produce a different notice for each state. A covered entity that conducts business both as part of an organized health care arrangement or affiliated covered entity and as an independent enterprise (e.g., a physician who sees patients through an on-call arrangement with a hospital and through an independent private practice) may want to adopt different privacy practices with respect to each line of business; such a covered entity would be required to produce a different notice describing the practices for each line of business. Covered entities must produce notices that accurately describe the privacy practices that are relevant to the individuals receiving the notice." Preamble, page 82548.

[9] **Federal agencies:** "We note that all federal agencies must still comply with the Privacy Act of 1974. This means that federal agencies that are covered entities or have covered health care components must comply with the notice requirements of the Privacy Act as well as those included in this rule." Preamble, page 82548.

[10] "**For example**, if a group health plan maintains both fully-insured and self-insured arrangements, the group health plan must, at a minimum, maintain and provide a notice that describes its privacy practices with respect to protected health information it creates or receives through the self-insured arrangements. This notice would be distributed to all participants in the self-insured arrangements (in accordance with § 164.520(c)(1)) and would also be available on request to other persons, including participants in the fully-insured arrangements." Preamble, pages 82547-8.

(ii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and that creates or receives protected health information in addition to summary health information as defined in § 164.504(a) or information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, must:

(A) Maintain a notice under this section; and

(B) Provide such notice upon request to any person. The provisions of paragraph (c)(1) of this section do not apply to such group health plan.

(iii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and does not create or receive protected health information other than summary health information as defined in § 164.504(a) or information on whether an individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, is not required to maintain or provide a notice under this section.

(3) Exception for inmates. An inmate does not have a right to notice under this section, and the requirements of this section do not apply to a correctional institution[11] that is a covered entity.

(b) Implementation specifications: content of notice.[12]

(1) Required elements.[13] The covered entity must provide[14] a notice that is written in plain language[15] and that contains the elements required by this paragraph.

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[11] **Inmates:** "No person, including a current or former inmate, has the right to notice of such a covered entity's privacy practices." Preamble, page 828548.

[12] **Notice requirements not exclusive:** "[T]he requirements for the content of the notice are not intended to be exclusive. As with the rest of the rule, we specify minimum requirements, not best practices. Covered entities may want to include more detail." Preamble, page 82548.

[13] **Layered notice:** "Covered entities may use a "layered" notice to implement the HIPAA Privacy Rule's requirements, so long as the elements required by 45 CFR 164.520(b) are included in the document that is provided to the individual. For example, a covered entity may satisfy the notice requirements by providing the individual with both a short notice that briefly summarizes the individual's rights, as well as other information; and a longer notice, layered beneath the short notice, that contains all of the elements required by the Privacy Rule. Providing the notice in this fashion is a helpful tool to assure that more individuals will realize that important information is contained in the notice." Guidance, December 4, 2002

[14] **Illiterates:** "We also encourage covered entities to be attentive to the needs of individuals who cannot read. For example, an employee of the covered entity could read the notice to individuals upon request or the notice could be incorporated into a video presentation that is played in the waiting area." Preamble, page 82549.

[15] **Meaning of "plain language":** "A covered entity can satisfy the plain language requirement if it makes a reasonable effort to: organize material to serve the needs of the reader; write short sentences in the active voice, using "you" and other pronouns; use common, everyday words in sentences; and divide material into short sections. We do not require particular formatting specifications …." Preamble, page 82548-9.

Non-English: "[A]ny covered entity that is a recipient of federal financial assistance is generally obligated under Title VI of the Civil Rights Act of 1964 to provide material ordinarily distributed to the public in the primary languages of persons with limited English proficiency in the recipients' service areas. Specifically, this Title VI obligation provides that, where a significant number or proportion of the population eligible to be served or likely to be directly affected by a federally assisted program needs service or information in a language other than English in order to be effectively informed of or participate in the program, the recipient shall take reasonable steps, considering the scope of the program and the size and concentration of such population, to provide information in languages appropriate to such persons. For covered entities

(i) Header. The notice must contain the following statement as a header or otherwise prominently displayed: "THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY."

(ii) Uses and disclosures. The notice must contain:

(A) A description, including at least one example, of the types of uses and disclosures that the covered entity is permitted by this subpart to make for each of the following purposes: treatment, payment, and health care operations.

(B) A description of each[16] of the other purposes for which the covered entity is permitted or required by this subpart to use or disclose protected health information without the individual's written authorization[17].

(C) If a use or disclosure for any purpose described in paragraphs (b)(1)(ii)(A) or (B) of this section is prohibited or materially limited by other applicable law, the description of such use or disclosure must reflect the more stringent law as defined in § 160.202.

(D) For each purpose described in paragraph (b)(1)(ii)(A) or (B) of this section, the description must include sufficient detail to place the individual on notice of the uses and disclosures that are permitted or required by this subpart and other applicable law.

(E) A statement that other uses and disclosures will be made only with the individual's written authorization and that the individual may revoke such authorization as provided by § 164.508(b)(5).

(iii) Separate statements for certain uses or disclosures.[18] If the covered entity intends to engage in any of the following activities, the description required by paragraph (b)(1)(ii)(A) of this section must[19] include a separate statement, as applicable, that:

(A) The covered entity may contact the individual to provide appointment reminders or information about treatment alternatives or other heath-related benefits and services that may be of interest to the individual;

(B) The covered entity may contact the individual to raise funds for the covered entity; or

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not subject to Title VI, the Title VI standards provide helpful guidance for effectively communicating the content of their notices to non-English speaking populations." Preamble, page 82549.

[16] **Describable disclosures:** "Covered entities must separately describe each purpose for which they are permitted to use or disclose protected health information under this rule without authorization, and must do so in sufficient detail to place the individual on notice of those uses and disclosures.… This requirement is intended to inform individuals of all the uses and disclosures that the covered entity is legally required or permitted to make under applicable law, even if the covered entity does not anticipate actually making such uses and disclosures." Preamble, page 82549.

"Covered entities may wish to highlight or otherwise emphasize any material modifications that it has made, in order to help the individual recognize such changes." Preamble, page 82550.

[17] Before August 14, 2002 amendment, read "consent or authorization".

[18] See section 164.502(i), which requires disclosures to be consistent with the notice.

[19] **Otherwise prohibited:** "If the covered entity does not include these statements in its notice, it is prohibited from using or disclosing protected health information for these activities without authorization." Preamble, page 82549.

(C) A group health plan, or a health insurance issuer or HMO with respect to a group health plan, may disclose protected health information to the sponsor of the plan.

(iv) Individual rights. The notice must contain a statement of the individual's rights with respect to protected health information and a brief description of how[20] the individual may exercise these rights, as follows:

(A) The right to request restrictions on certain uses and disclosures of protected health information as provided by § 164.522(a), including a statement that the covered entity is not required to agree to a requested restriction;

(B) The right to receive confidential communications of protected health information as provided by § 164.522(b), as applicable;

(C) The right to inspect and copy protected health information as provided by § 164.524[21];

(D) The right to amend protected health information as provided by § 164.526;

(E) The right to receive an accounting of disclosures of protected health information as provided by § 164.528; and

(F) The right of an individual, including an individual who has agreed to receive the notice electronically in accordance with paragraph (c)(3) of this section, to obtain a paper copy of the notice from the covered entity upon request.

(v) Covered entity's duties. The notice must contain:

(A) A statement that the covered entity is required by law to maintain the privacy of protected health information and to provide individuals with notice of its legal duties and privacy practices with respect to protected health information;

(B) A statement that the covered entity is required to abide by the terms of the notice currently in effect; and

(C) For the covered entity to apply a change in a privacy practice that is described in the notice to protected health information that the covered entity created or received prior to issuing a revised notice, in accordance with § 164.530(i)(2)(ii), a statement that it reserves the right to change the terms of its notice and to make the new notice provisions effective for all protected health information that it maintains. The statement must also describe how it will provide individuals with a revised notice.[22]

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[20] "… with respect to the covered entity …" Preamble, page 82549.

[21] **Descriptions must only be general:** "Similarly, we require covered entities to have policies and procedures for assuring individuals access to protected health information about them. While such policies and procedures will need to include documentation of the designated record sets subject to access, who is authorized to determine when information will be withheld from an individual, and similar details, the notice need only explain generally that individuals have the right to inspect and copy information about them, and tell individuals how to exercise that right." Preamble, page 82548.

[22] **Statement required for retroactivity of changes:** "Under § 164.530(i), a covered entity that wishes to change its practices over time without segregating its records according to the notice in effect at the time the records were created must reserve the right to do so in its notice. For example, a covered hospital that states in its notice that it will only make public health disclosures required by law, and that does not reserve the right to change this practice, is prohibited from

(vi) Complaints. The notice must contain a statement that individuals may complain to the covered entity and to the Secretary if they believe their privacy rights have been violated, a brief description of how the individual may file a complaint with the covered entity, and a statement that the individual will not be retaliated against for filing a complaint.

(vii) Contact. The notice must contain the name, or title, and telephone number of a person or office to contact for further information as required by § 164.530(a)(1)(ii).[23]

(viii) Effective date. The notice must contain the date on which the notice is first in effect, which may not be earlier than the date on which the notice is printed or otherwise published.

(2) Optional elements.

(i) In addition to the information required by paragraph (b)(1) of this section, if a covered entity elects to limit the uses or disclosures that it is permitted to make under this subpart[24], the covered entity may describe its more limited uses or disclosures in its notice, provided that the covered entity may not include in its notice a limitation affecting its right to make a use or disclosure that is required by law or permitted by § 164.512(j)(1)(i)[25].

(ii) For the covered entity to apply a change in its more limited uses and disclosures to protected health information created or received prior to issuing a revised notice, in accordance with § 164.530(i)(2)(ii), the notice must include the statements required by paragraph (b)(1)(v)(C) of this section.

(3) Revisions to the notice. The covered entity must promptly revise[26] and distribute[27] its notice whenever there is a material change to the uses or disclosures, the individual's rights, the covered entity's legal duties, or other privacy practices stated in the notice. Except when required by law, a material change to any term of the notice may not be implemented prior to the effective date of the notice in which such material change is reflected.

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making any discretionary public health disclosures of protected health information created or received during the effective period of that notice. If the covered hospital wishes at some point in the future to make discretionary disclosures for public health purposes, it must revise its notice to so state, and must segregate its records so that protected health information created or received under the prior notice is not disclosed for discretionary public health purposes. This hospital may then make discretionary public health disclosures of protected health information created or received after the effective date of the revised notice." Preamble, page 82550-1.

[23] "A covered entity must designate a contact person or office who is responsible for receiving complaints under this section and who is able to provide further information about matters covered by the notice required by § 164.520."

[24] **Protections greater then required:** "We anticipate that some covered entities will want to distinguish themselves on the basis of their more stringent privacy practices. For example, covered health care providers who routinely treat patients with particularly sensitive conditions may wish to assure their patients that, even though the law permits them to disclose information for a wide array of purposes, the covered health care provider will only disclose information in very specific circumstances, as required by law, and to avert a serious and imminent threat to health or safety." Preamble, page 82550.

[25] "… necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public."

[26] **Highlighting changes:** "Covered entities may wish to highlight or otherwise emphasize any material modifications that it has made, in order to help the individual recognize such changes." Preamble, page 82550.

[27] **Mailing not required:** "The HIPAA Privacy Rule does not require a covered health care provider to mail out its revised notice or otherwise notify patients by mail of changes to the notice. " Guidance, December 4, 2002

(c) Implementation specifications: provision of notice. A covered entity must make the notice required by this section available on request to any person[28] and to individuals as specified in paragraphs (c)(1) through (c)(3) of this section, as applicable.

(1) Specific requirements for health plans.

(i) A health plan must provide notice:

(A) No later than the compliance date for the health plan, to individuals then covered by the plan;

(B) Thereafter, at the time of enrollment, to individuals who are new enrollees; and

(C) Within 60 days of a material revision to the notice, to individuals then

covered by the plan.

(ii) No less frequently than once every three years, the health plan must notify individuals then covered by the plan of the availability of the notice and how to obtain the notice.[29]

(iii) The health plan satisfies the requirements of paragraph (c)(1) of this section if notice is provided to the named insured of a policy under which coverage is provided to the named insured and one or more dependents.[30]

(iv) If a health plan has more than one notice, it satisfies the requirements of paragraph (c)(1) of this section by providing the notice that is relevant to the individual or other person requesting the notice.[31]

(2) Specific requirements for certain covered health care providers. A covered health care provider that has a direct treatment relationship with an individual[32] must:

(i) Provide[33] the notice:

(A) No later than the date of the first service delivery[34], including service delivered electronically, to such individual[35] after the compliance date for the covered health care provider;[36] or

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[28] **Publicly available:** "The requestor does not have to be a current patient or enrollee. We intend the notice to be a public document that people can use in choosing between covered entities." Preamble, page 82551.

[29] **Distribution required only once:** "Unlike the proposed rule, we do not require health plans to distribute the notice every three years." Preamble, page 82551.

[30] "**For example**, if an employee of a firm and her three dependents are all covered under a single health plan policy, that health plan can satisfy the initial distribution requirement by sending a single copy of the notice to the employee rather than sending four copies, each addressed to a different member of the family." Preamble, page 82551.

[31] "**For example**, a health insurance issuer may have contracts with two different group health plans. One contract specifies that the issuer may use and disclose protected health information about the participants in the group health plan for research purposes without authorization (subject to the requirements of this rule) and one contract specifies that the issuer must always obtain authorizations for these uses and disclosures. The issuer accordingly develops two notices reflecting these different practices and satisfies its distribution requirements by providing the relevant notice to the relevant group health plan participants." Preamble, page 82551.

[32] **Indirect treatment providers:** "Covered health care providers that have indirect treatment relationships with individuals are only required to produce the notice upon request, as described above." Preamble, page 82551.

[33] **Business Associates:** “A covered entity may use a business associate to distribute its notice to individuals.” Guidance, December 4, 2002.

(B) In an emergency treatment situation, as soon as reasonably practicable after the emergency treatment situation.[37]

(ii) Except in an emergency treatment situation, make a good faith effort to obtain[38] a written[39] acknowledgment[40] of receipt[41] of the notice provided in accordance with paragraph (c)(2)(i) of this

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[34] **Initial treatment by phone:** "A health care provider who first treats a patient over the phone satisfies the notice provision requirements of the Privacy Rule by mailing the notice to the individual the same day, if possible. To satisfy the requirement that the provider also make a good faith effort to obtain the individual's acknowledgment of the notice, the provider may include a tear-off sheet or other document with the notice that requests that the acknowledgment be mailed back to the provider. The health care provider is not in violation of the Rule if the individual chooses not to mail back an acknowledgment; and a file copy of the form sent to the patient would be adequate documentation of the provider's good faith effort to obtain the acknowledgment." Guidance, December 4, 2002

Scheduling only does not trigger notice delivery: "Where a health care provider's initial contact with a patient is simply to schedule an appointment or a procedure, or to collect information in anticipation of an appointment or a procedure, the Privacy Rule's requirements for providing the notice and obtaining a patient's acknowledgment of the notice may be satisfied at the time the individual arrives at the provider's facility for his or her appointment or procedure." Guidance, December 4, 2002

[35] **Personal representatives:** "In cases where the individual has a personal representative, as is generally the case when a parent brings a child in for treatment, the provider satisfies the notice distribution requirements by providing the notice to the personal representative (e.g., the child's parent), and making a good faith effort to obtain the personal representative's acknowledgment of the notice." Guidance, December 4, 2002

[36] **Options for providing:** "Covered providers may satisfy this requirement by sending the notice to all of their patients at once, by giving the notice to each patient as he or she comes into the provider's office or facility or contacts the provider electronically, or by some combination of these approaches." Preamble, page 82551.

"No special or separate mailings or distributions are required to satisfy the Privacy Rule's notice distribution requirements. … However, … direct treatment providers, other than in emergency situations, … must make a good faith effort to obtain the individual's written acknowledgment of receipt of the notice." Guidance, December 4, 2002

[37] Added in August 14, 2002 amendment.

[38] **Only one acknowledgement required:** "A covered health care provider with a direct treatment relationship with individuals is required to make a good faith effort to obtain an individual's acknowledgment of receipt of the notice only at the time the provider first gives the notice to the individual--that is, at first service delivery." Guidance, December 4, 2002

Mailed Notice: "A health care provider who first treats a patient over the phone satisfies the notice provision requirements of the Privacy Rule by mailing the notice to the individual the same day, if possible. To satisfy the requirement that the provider also make a good faith effort to obtain the individual's acknowledgment of the notice, the provider may include a tear-off sheet or other document with the notice that requests that the acknowledgment be mailed back to the provider. The health care provider is not in violation of the Rule if the individual chooses not to mail back an acknowledgment; and a file copy of the form sent to the patient would be adequate documentation of the provider's good faith effort to obtain the acknowledgment." Guidance, December 4, 2002

[39] **Electronic acknowledgement: "**appointment. For service provided electronically, the Department believes that, just as a notice may be delivered electronically, a provider should be capable of capturing the individual's acknowledgment of receipt electronically in response to that transmission." Preamble to final revisions, 67 FR 53241.

[40] **Purpose of acknowledgment:** "The notice acknowledgment process is intended to provide a formal opportunity for the individual to engage in a discussion with a health care provider about privacy." Preamble to final revisions, 67 FR 53240.

Form of acknowledgement: "Those providers that choose to obtain consent from individuals have discretion to design one form that includes both a consent and the acknowledgment of receipt of the notice." Guidance, December 4, 2002. "The Department would not consider a receptionist's notation in a computer system to be an individual's written acknowledgment." Preamble to final revisions, 67 FR 53242. "For example, the final Rule does not require an individual's signature to be on the notice. Instead, a covered health provider is permitted, for example, to have the individual sign a separate sheet or list, or to simply initial a cover sheet of the notice to be retained by the provider. Alternatively, a pharmacist is permitted to have the individual sign or initial an acknowledgment within the log book that patients already sign when they pick up prescriptions, so long as the individual is clearly informed on the log book of what they are

section, and if not obtained[42], document its good faith efforts[43] to obtain such acknowledgment and the reason why the acknowledgment was not obtained; [44]

(iii) If the covered health care provider maintains a physical service delivery site:

(A) Have the notice available at the service delivery site for individuals to request to take with them; and

(B) Post[45] the notice in a clear and prominent location where it is reasonable to expect individuals seeking service from the covered health care provider to be able to read the notice; and

(iv) Whenever the notice is revised, make the notice available upon request on or after the effective date of the revision and promptly comply with the requirements of paragraph (c)(2)(iii) ~~(ii)~~ of this section, if applicable.

(3) *Specific requirements for electronic notice.*

(i) A covered entity that maintains a web site that provides information about the covered entity's customer services or benefits must prominently post its notice on the web site and make the notice available electronically through the web site.

(ii) A covered entity may provide the notice required by this section to an individual by e-mail, if the individual agrees to electronic notice and such agreement has not been withdrawn. If the covered entity knows that the e-mail transmission has failed, a paper copy of the notice must be provided to the individual. Provision of electronic notice by the covered entity will satisfy the provision requirements of paragraph(c) of this section when timely made in accordance with paragraph (c)(1) or (2) of this section.

(iii) For purposes of paragraph (c)(2)(i) of this section, if the first service delivery to an individual is delivered electronically, the covered health care provider must provide electronic notice automatically

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acknowledging and the acknowledgment is not also used as a waiver or permission for something else (such as a waiver to consult with the pharmacist)." Preamble to final revisions, 67 FR 53240..

[41] **Understanding:** Health care providers have no obligation to insure that the recipient understands the notice, other then to meet the content requirements. See, for example, Preamble to final revisions, 67 FR 53241.

[42] **Failure to get acknowledgement not a violation:** "Department's position is that a failure by a covered entity to obtain an individual's acknowledgment, assuming it otherwise documented its good faith effort (as required by § 164.520(c)(2)(ii)), will not be considered a violation of this Rule." Preamble to final revisions, 67 FR 53242.

[43] **Acknowledgement problems:** "This provision also is intended to allow covered health care providers flexibility to deal with a variety of circumstances in which obtaining an acknowledgment is problematic." Preamble to final revisions, 67 FR 53240.

[44] Added in August 14, 2002 amendment.

[45] **Form of Posted Notice:** "The Privacy Rule … does not prescribe any specific format for the posted notice, just that it include the same information that is distributed directly to the individual. Covered health care providers have discretion to design the posted notice in a manner that works best for their facility, which may be to simply post a copy of the pages of the notice that is provided directly to individuals." Guidance, December 4, 2002

and contemporaneously in response to the individual's first request for service.[46] The requirements in paragraph (c)(2)(ii) of this section apply to electronic notice.[47]

(iv) The individual who is the recipient of electronic notice retains the right to obtain a paper copy of the notice from a covered entity upon request.

(d) Implementation specifications: joint notice by separate covered entities.[48] Covered entities that participate in organized health care arrangements[49] may comply with this section by a joint notice, provided that:

(1) The covered entities participating in the organized health care arrangement agree to abide by the terms of the notice with respect to protected health information created or received by the covered entity as part of its participation in the organized health care arrangement;

(2) The joint notice meets the implementation specifications in paragraph (b) of this section, except that the statements required by this section may be altered to reflect the fact that the notice covers more than one covered entity; and

(i) Describes with reasonable specificity the covered entities, or class of entities, to which the joint notice applies;

(ii) Describes with reasonable specificity the service delivery sites, or classes of service delivery sites, to which the joint notice applies; and

(iii) If applicable, states that the covered entities participating in the organized health care arrangement will share protected health information with each other, as necessary to carry out treatment, payment, or health care operations relating to the organized health care arrangement.

(3) The covered entities included in the joint notice must provide the notice to individuals in accordance with the applicable implementation specifications of paragraph (c) of this section. Provision of the joint notice to an individual by any one of the covered entities included in the joint notice will satisfy the provision requirement of paragraph (c) of this section with respect to all others covered by the joint notice.

(e) *Implementation specifications: Documentation.* A covered entity must document compliance with the notice requirements, as required by § 164.530(j), by retaining copies of the notices issued by the covered entity

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[46] "**For example**, the first time an individual requests to fill a prescription through a covered internet pharmacy, the pharmacy must automatically and contemporaneously provide the individual with the pharmacy's notice of privacy practices." Preamble, page 82551-2.

[47] Last sentence added in August 14, 2002 amendment.

[48] "Typical **examples** where this policy may be useful are health care facilities where physicians and other providers who have offices elsewhere also provide services at the facility (e.g. hospital staff privileges, physicians visiting their patients at a residential facility). In these cases, a single notice may cover both the physician and the facility, if the above conditions are met. The physician is required to have a separate notice covering the privacy practices at the physician's office if those practices are different than the practices described in the joint notice." Preamble, page 82552.

[49] See definition at §164.501.

Affiliates notice: "We note that, under § 164.504(d), covered entities that are under common ownership or control may designate themselves as a single affiliated covered entity. Joint notice requirements do not apply to such entities. Single affiliated covered entities must produce a single notice, consistent with the requirements described above for any other covered entity. Covered entities under common ownership or control that elect not to designate themselves as a single affiliated covered entity, however, may elect to produce a joint notice if they meet the definition of an organized health care arrangement." Preamble, page 82552

and, if applicable, any written acknowledgments of receipt of the notice or documentation of good faith efforts to obtain such written acknowledgment, in accordance with paragraph (c)(2)(ii) of this section.[50]

* * *

Preamble to final rule
65 FR 82552

"The joint notice must meet all of the requirements described above. The covered entities must agree to abide by the terms of the notice with respect to protected health information created or received by the covered entities as part of their participation in the organized health care arrangement. In addition, the joint notice must reasonably identify the covered entities, or class of covered entities, to which the joint notice applies and the service delivery sites, or classes of service delivery sites, to which the joint notice applies. If the covered entities participating in the organized health care arrangement will share protected health information with each other as necessary to carry out treatment, payment, or health care operations relating to the arrangement, that fact must be stated in the notice.

"Typical examples where this policy may be useful are health care facilities where physicians and other providers who have offices elsewhere also provide services at the facility (e.g. hospital staff privileges, physicians visiting their patients at a residential facility). In these cases, a single notice may cover both the physician and the facility, if the above conditions are met. The physician is required to have a separate notice covering the privacy practices at the physician's office if those practices are different than the practices described in the joint notice."

[50] Before August 14, 2002 amendment, this subsection read: "(e) *Implementation specifications: Documentation.* A covered entity must document compliance with the notice requirements by retaining copies of the notices issued by the covered entity as required by § 164.530(j)."

Preamble to final revisions
67 FR 53241

"*Comment:* A few commenters requested clarification as to how the Department intended the notice acknowledgment process to be implemented within an affiliated covered entity or an ***organized health care arrangement*** (***OHCA***).

"*Response:* The requirement for an individual's written acknowledgment of the notice corresponds with the requirement that the notice be provided to the individual by certain health care providers at first service delivery, regardless of whether the notice itself is the joint notice of an ***OHCA***, the notice of an affiliated covered entity, or the notice of one entity. With respect to an ***OHCA***, the Privacy Rule permits covered entities that participate in an ***OHCA*** to satisfy the notice requirements through the use of a joint notice, provided that the relevant conditions of § 164.520(d) are met. Section 164.520(d)(3) further provides that provision of a joint notice to an individual by any one of the covered entities included in the joint notice satisfies the notice provision requirements at § 164.520(c) with respect to all others covered by the joint notice. Thus, a health care provider with a direct treatment relationship with an individual that is participating in an ***OHCA*** only need make a good faith effort to obtain the individual's acknowledgment of the joint notice if that provider is the covered entity within the ***OHCA*** that is providing the joint notice to the individual. Where the joint notice is provided to the individual by a participating covered entity other than a provider with a direct treatment relationship with the individual, no acknowledgment need be obtained. However, covered entities that participate in an ***OHCA*** are not required to utilize a joint notice and may maintain separate notices. In such case, each covered health care provider with a direct treatment relationship within the ***OHCA*** must make a good faith effort to obtain the individual's acknowledgment of the notice he or she provides."

OCR HIPAA Privacy Guidance
December 3, 2002

"Q: We participate in an organized health care arrangement (OHCA). How are we to comply with the HIPAA Privacy Rule's requirements for providing notices and obtaining individuals' acknowledgments of the notice?

"A: Health care providers and other covered entities that participate in an organized health care arrangement (OHCA) may use a single, joint notice that covers all of the participating covered entities (provided that the conditions at 45 CFR 164.520(d) are met), or may each maintain separate notices. Where a joint notice is provided to an individual by any one of the covered entities to which the joint notice applies, the Privacy Rule's requirements for providing the notice are satisfied for all others covered by the joint notice. If the joint notice is provided to an individual by a direct treatment provider participating in the OHCA, the provider must make a good faith effort to obtain the individual's written acknowledgment of receipt of the joint notice. Where the joint notice is provided to the individual by a participating covered entity other than a direct treatment provider, no acknowledgment need be obtained. However, where covered entities participating in an OHCA choose to maintain separate notices, each covered entity from which an individual obtains services must provide its notice to the individual in accordance with the applicable requirements of 45 CFR 164.520(c). In addition, each direct treatment provider within the OHCA must make a good faith effort to obtain the individual's acknowledgment of the notice he or she provides."

How do the notice requirements affect OHCAs?

Question: We participate in an organized health care arrangement (OHCA). How are we to comply with the HIPAA Privacy Rule's requirements for providing notices and obtaining individuals' acknowledgements of the notice?

Answer: Health care providers and other covered entities that participate in an organized health care arrangement (OHCA) may use a single, joint notice that covers all of the participating covered entities (provided that the conditions at 45 CFR 164.520(d) are met), or may each maintain separate notices. Where a joint notice is provided to an individual by any one of the covered entities to which the joint notice applies, the Privacy Rule's requirements for providing the notice are satisfied for all others covered by the joint notice. If the joint notice is provided to an individual by a direct treatment provider participating in the OHCA, the provider must make a good faith effort to obtain the individual's written acknowledgment of receipt of the joint notice. Where the joint notice is provided to the individual by a participating covered entity other than a direct treatment provider, no acknowledgment need be obtained.

However, where covered entities participating in an OHCA choose to maintain separate notices, each covered entity from which an individual obtains services must provide its notice to the individual in accordance with the applicable requirements of 45 CFR 164.520(c). In addition, each direct treatment provider within the OHCA must make a good faith effort to obtain the individual's acknowledgment of the notice he or she provides.

Answer ID *337,* ***Date Updated*** *07/18/2003*

Operational Issues

Business Associates

§ 164.502 Uses and disclosures of protected health information: general rules.

* * *

(e) (1) *Standard: Disclosures to business associates.*

(i) A covered entity may disclose protected health information to a business associate and may allow a business associate to create or receive protected health information on its behalf, if the covered entity obtains satisfactory assurance that the business associate will appropriately safeguard the information.[51]

(ii) This standard does not apply:

(A) With respect to disclosures by a covered entity to a health care provider concerning the treatment of the individual[52];

(B) With respect to disclosures by a group health plan or a health insurance issuer or HMO with respect to a group health plan to the plan sponsor, to the extent that the requirements of § 164.504(f) apply and are met; or

(C) With respect to uses or disclosures by a health plan that is a government program providing public benefits, if eligibility for, or enrollment in, the health plan is determined by an agency other than the agency administering the health plan, or if the protected health information used to determine enrollment or eligibility in the health plan is collected by an agency other than the agency administering the health plan, and such activity is authorized by law, with respect to the collection and sharing of individually identifiable health information for the performance of such functions by the health plan and the agency other than the agency administering the health plan.

(iii) A covered entity that violates the satisfactory assurances it provided as a business associate of another covered entity will be in noncompliance with the standards, implementation specifications, and requirements of this paragraph and § 164.504(e).

* * *

"Are business associate agreements required within an organized health care arrangement?

[51] "By law, the Privacy Rule applies only to health plans, health care clearinghouses, and certain health care providers. In today's health care system, however, most health care providers and health plans do not carry out all of their health care activities and functions by themselves; they require assistance from a variety of contractors and other businesses. In allowing providers and plans to give protected health information (PHI) to these "business associates," the Privacy Rule conditions such disclosures on the provider or plan obtaining, typically by contract, satisfactory assurances that the business associate will use the information only for the purposes for which they were engaged by the covered entity, will safeguard the information from misuse, and will help the covered entity comply with the covered entity's duties to provide individuals with access to health information about them and a history of certain disclosures (e.g., if the business associate maintains the only copy of information, it must promise to cooperate with the covered entity to provide individuals access to information upon request). PHI may be disclosed to a business associate *only* to help the providers and plans carry out their health care functions – not for independent use by the business associate." *Initial DHHS Guidance, July 6, 2001*

[52] "… we allow covered entities to make any disclosure of protected health information for treatment purposes to a health care provider without a business associate arrangement. This provision includes all activities that fall under the definition of treatment." (Preamble, page 82504)

“Question: Are covered entities that engage in joint activities under an organized health care arrangement (OHCA) required to have business associate contracts with each other?

“Answer: No. Covered entities that participate in an OHCA are permitted to share protected health information for the joint health care activities of the OHCA without entering into business associate contracts with each other. Of course, each such entity is independently required to observe its obligations under the HIPAA Privacy Rule with respect to protected health information.”

***OCR Answer ID** 242, **Date Updated** 07/18/2003*

OCR HIPAA Privacy Guidance
December 3, 2002

“Q: Are covered entities that engage in joint activities under an organized health care arrangement (OHCA) required to have business associate contracts with each other?
“A: No. Covered entities that participate in an OHCA are permitted to share protected health information for the joint health care activities of the OHCA without entering into business associate contracts with each other. Of course, each such entity is independently required to observe its obligations under the HIPAA Privacy Rule with respect to protected health information.”

§ 160.103 Definitions. Except as otherwise provided, the following definitions apply to this subchapter:

* * *

Business associate:

(1) Except as provided in paragraph (2) of this definition, *business associate* means, with respect to a covered entity, a person who:

(i) On behalf of such covered entity or of an ***organized health care arrangement*** (as defined in § 164.501 of this subchapter) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, performs, or assists in the performance of:

(A) A function or activity involving the use or disclosure of individually identifiable health information, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management, and repricing; or

(B) Any other function or activity regulated by this subchapter; or

(ii) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in § 164.501 of this subchapter), management, administrative, accreditation, or financial services to or for such covered entity, or to or for an ***organized health care arrangement*** in which the covered entity participates, where the provision of the service involves the disclosure of individually identifiable health information from such covered

entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

(2) A covered entity participating in an ***organized health care arrangement*** that performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such ***organized health care arrangement***, or that provides a service as described in paragraph (1)(ii) of this definition to or for such ***organized health care arrangement***, does not, simply through the performance of such function or activity or the provision of such service, become a business associate of other covered entities participating in such ***organized health care arrangement***.[53]

(3) A covered entity may be a business associate of another covered entity.

Do a health insurer/HMO and a group health plan have a business associate relationship?

Question: Is a health insurance issuer or HMO who provides health insurance or health coverage to a group health plan a business associate of the group health plan?

Answer: A health insurance issuer or HMO does not become a business associate simply by providing health insurance or health coverage to a group health plan. The relationship between the group health plan and the health insurance issuer or HMO is defined by the Privacy Rule as an organized health care arrangement (OHCA), with respect to the individuals they jointly serve or have served. Thus, these covered entities are permitted to share protected health information that relates to the joint health care activities of the OHCA. However, where a group health plan contracts with a health insurance issuer or HMO to perform functions or activities or to provide services that are in addition to or not directly related to the joint activity of providing insurance, the health insurance issuer or HMO may be a business associate with respect to those additional functions, activities, or services.

***Answer ID** 254, **Date Updated** 03/03/2003*

Health Care Operations

§ 164.506 Uses or disclosures to carry out treatment, payment, or health care operations.

(a) *Standard: Permitted uses and disclosures.* Except with respect to uses or disclosures that require an authorization under § 164.508(a)(2) and (3), a covered entity may use or disclose protected health information for treatment, payment, or health care operations as set forth in paragraph (c) of this section, provided that such use or disclosure is consistent with other applicable requirements of this subpart.

* * *

(c) *Implementation specifications: Treatment, payment, or health care operations*.

(1) A covered entity may use or disclose protected health information for its own treatment, payment, or health care operations.

[53] "The fact that the entities participate in joint health care operations or other joint activities, or pursue common goals through a joint activity, does not mean that one party is performing a function or activity on behalf of the other party (or is providing a specified services to or for the other party)." Preamble to final rule, 65 FR 82476.

(2) A covered entity may disclose protected health information for treatment activities of a health care provider.

(3) A covered entity may disclose protected health information to another covered entity or a health care provider for the payment activities of the entity that receives the information.

(4) A covered entity may disclose protected health information to another covered entity for health care operations activities of the entity that receives the information, if each entity either has or had a relationship with the individual who is the subject of the protected health information being requested, the protected health information pertains to such relationship, and the disclosure is:

(i) For a purpose listed in paragraph (1) or (2) of the definition of health care operations; or

(ii) For the purpose of health care fraud and abuse detection or compliance.

(5) A covered entity that participates in an ***organized health care arrangement*** may disclose protected health information about an individual to another covered entity that participates in the ***organized health care arrangement*** for any health care operations activities of the ***organized health care arrangement***.[54]

[54] "Additionally, as clarified by § 164.506(c)(5), covered entities that participate in an ***OHCA*** may share protected health information for the health care operations of the ***OHCA***, without the condition that each covered entity have a relationship with the individual who is the subject of the information. The Department believes that such provisions provide adequate avenues for covered entities to obtain the information they need for health care operations activities, without eliminating appropriate privacy protections and conditions on such disclosures." Preamble to final revisions, 67 FR 53217

"The Department also was not persuaded by the comments that the proposal should be broadened to allow disclosures for other types of health care operations activities, such as resolution of internal grievances, customer service, or medical review or auditing activities. The Department believes that the provisions at § 164.506(c)(5), which permit covered entities that participate in an ***OHCA*** to share information for any health care operations activities of the ***OHCA***, adequately provides for such disclosures. For example, a health plan and the health care providers in its network that participate as part of the same ***OHCA*** are permitted to share information for any of the activities listed in the definition of ''health care operations.'' The Department understands the need for entities participating in these joint arrangements to have shared access to information for health care operations purposes and intended the ***OHCA*** provisions to provide for such access. Where such a joint arrangement does not exist and fully identifiable health information is needed, one covered entity may disclose protected health information for another covered entity's health care operations pursuant to an individual's authorization as required by § 164.508. In addition, as described above, a covered entity also may disclose protected health information as part of a limited data set, with direct identifiers removed, for such purposes, as permitted by § 164.514(e)." Preamble to final revisions, 67 FR 53217

"[T]he Department clarifies that the Privacy Rule restricts the sharing of protected health information between covered and non-covered functions, regardless of whether the information is shared within a single covered entity or a hybrid entity, or among affiliated covered entities or covered entities participating in an ***OHCA***. Such uses and disclosures may only be made as permitted by the Rule." Preamble to final revisions, 67 FR 53206.

Questions and Discussion

1. Who?

a. Is it already an OHCA?

b. Can your providers opt in and out, or must it be “all or nothing”?

2. How?

a. Must it be in the medical staff bylaws?

b. Must it be a disciplinary offense?

c. Can you use a separate contract?

d. Other?

3. What are the benefits?

a. Ease of notice

b. Physician relations

c. Any others?

4. What are the disadvantages?

a. Consequences of physician non-compliance?

b. Another source of confrontation with physicians

c. Disappointed expectations

d. Others?