

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Voice - (202) 619-0403 TDD - (202) 619-3257 Fax - (202) 619-3818  
 Http://www.hhs.gov/ocr/

**OFFICE OF THE SECRETARY**

Director  
 Office for Civil Rights  
 200 Independence Ave., SW Rm 506F  
 Washington, DC 20201

April 23, 2003

George H. Shyn, Pharm D  
 Pharmacist, Shyn's Pharmacy  
 3544 W Olympic Boulevard  
 Los Angeles, CA 90010

RECEIVED  
 GOULSTON & STORRS

JUL 10 2003

A.S.G.

Dear Dr. Shyn:

Thank you for your letter concerning whether Shyn's Pharmacy is considered a small health plan and as such qualifies for the one-year extension, until April 14, 2004, available to small health plans before compliance with the HIPAA Privacy Rule is required. At the outset, we note that pharmacies are typically considered health care providers under the Privacy Rule, rather than health plans, and the compliance date for all health care providers that are covered by the Privacy Rule is April 14, 2003. If a health care provider engages in activities that make it a "covered entity" under HIPAA, it is obligated to comply with the Privacy Rule as of April 14, 2003.

As defined by HIPAA, there are three categories of "covered entities:" health care providers who transmit any health information in electronic form in connection with a transaction for which the Secretary of HHS has adopted a standard; health plans; and health care clearinghouses. The determination whether a particular organization is a covered entity depends upon specific facts related to the entity's operations. Many entities create or obtain health information that identifies an individual, but do not meet the definition of a covered entity. Further, access to identifiable health information alone does not determine a covered entity status. And where providers are concerned, HIPAA applies only to those providers who conduct certain transactions electronically.

The Department has developed a covered entity "decision tool" that will help you determine whether, based on your circumstances, your organization is a health care provider and engages in the electronic transactions that trigger HIPAA coverage. This interactive tool, which provides a step-by-step guide to help individuals and entities assess whether they are covered, entities, may be accessed through the Office of Civil Rights (OCR) privacy website at <http://www.hhs.gov/ocr/hippa/whatsnew.html> or through the Centers for Medicare and Medicaid Services (CMS) HIPAA website at <http://www.cms.hhs.gov/hipaa/hipaa2/>.

OCR's website, <http://www.hhs.gov/ocr/hippa>, also offers significant additional information to help covered entities comply with the Privacy Rule. This website contains the full text of the Privacy Rule and other documents that will assist covered entities with their compliance efforts, such as updated Guidance containing some 200 frequently asked questions, fact sheets, Sample Business Associate Contract Provisions, and links to other helpful Department websites about

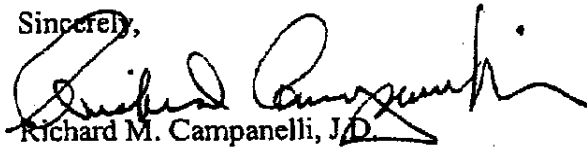
Page 2 - Mr. George Shyn

other aspects of HIPAA. In addition, OCR is developing other materials and videos tailored to specific groups, such as professional providers, institutional providers, health plans and state and local governments.

We trust that these resources will assist you in your efforts to determine how HIPAA and the Privacy Rule apply to Shyn's Pharmacy.

If we can be of further assistance, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Campanelli". The signature is fluid and cursive, with a long horizontal stroke at the end.

Richard M. Campanelli, J.D.

Director

Office for Civil Rights



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Voice - (202) 619-0403 TDD - (202) 619-3257 Fax - (202) 619-3818

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## OFFICE OF THE SECRETARY

Director

Office for Civil Rights

200 Independence Ave., SW Rm 506F

Washington, DC 20201

March 14, 2003

RECEIVED  
GOULSTON & STORRS

JUL 10 2003

A.S.G.

The Honorable Todd Russell Platts  
House of Representatives  
Washington, DC 20515

Dear Congressman Platts:

Thank you for your inquiry on behalf of your constituent, Mr. John Wurzbacher, who expressed concerns regarding the new health information privacy regulation (Privacy Rule). Your letter to Scott Whitaker, the HHS Assistant Secretary for Legislation, was forwarded to the Department's Office for Civil Rights (OCR) for reply. OCR is responsible for implementing and enforcing the Privacy Rule, issued pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Mr. Wurzbacher particularly sought assistance in determining whether the Community Progress Council, Inc., is subject to the requirements of HIPAA or the Privacy Rule. As defined by HIPAA, there are three categories of "covered entities": health care providers who transmit any health information in electronic form in connection with a transaction for which the Secretary of HHS has adopted a standard; health plans; and health care clearinghouses. The determination whether a particular organization is a covered entity depends upon specific facts related to the entity's operations. Many entities create or obtain health information that identifies an individual, but do not meet the definition of a covered entity. Further, access to identifiable health information alone does not determine a covered entity status. And where providers are concerned, HIPAA applies only to those providers who conduct certain transactions electronically.

Because such a fact-specific analysis is required, and since millions of organizations may meet the definition of covered entity, we are not able to respond to requests for determinations about whether particular organizations are "covered entities." However, the Department has developed a covered entity "decision tool" to assist in making these determinations. This interactive tool, which provides a step-by-step guide to help individuals and entities assess whether they are covered entities, may be accessed through the OCR privacy website at <http://www.hhs.gov/ocr/hipaa/whatsnew.html>, or through the Centers for Medicare and Medicaid Services (CMS) HIPAA web site at <http://www.cms.hhs.gov/hipaa/hipaa2/>.

The Office for Civil Right's website, <http://www.hhs.gov/ocr/hipaa/> also offers significant additional information to help covered entities comply with the Privacy Rule. This website contains the full text of the Privacy Rule and other documents that will assist covered entities with their compliance efforts, such as updated Guidance containing some 200 frequently asked questions, fact sheets, Sample Business Associate Contract Provisions, and links to other helpful

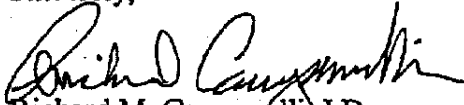
Page 2 - The Honorable Todd Platts

Department websites about other aspects of HIPAA. In addition, OCR is developing other materials and videos tailored to specific groups, such as professional providers, institutional providers, health plans and State and local governments.

We trust that these resources will assist Mr. Wurzbacher in his efforts to determine how HIPAA and the Privacy Rule apply to his organization.

If we can be of further assistance, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Campanelli". The signature is fluid and cursive, written over the printed name.

Richard M. Campanelli, J.D.

Director

Office for Civil Rights

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

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**OFFICE OF THE SECRETARY**

Director

Office for Civil Rights

200 Independence Ave., SW Rm 506F

Washington, DC 20201

April 16, 2003

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GOULSTON & STORRS

JUL 10 2003

**A.S.G.**The Honorable Jim Gerlach  
House of Representatives  
Washington, DC 20515

Dear Congressman Gerlach:

Thank you for your inquiry on behalf of your constituent, Mr. Scott Exley, who expressed concerns regarding the health information privacy regulation (Privacy Rule). Your letter to Scott Whitaker, the HHS Assistant Secretary for Legislation, was forwarded to the Department's Office for Civil Rights (OCR) for reply. OCR is responsible for implementing and enforcing the Privacy Rule, issued pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

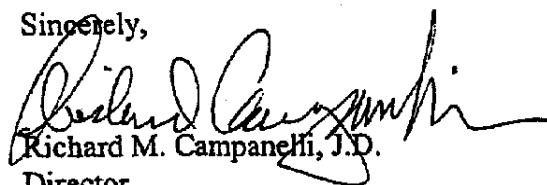
Mr. Exley expressed concern that the Privacy Rule does not appropriately protect identifiable patient information held by insurance carriers, thus permitting disclosures by them to employers and other third parties for numerous purposes. We hope he is pleased to learn that the Privacy Rule does limit the use and disclosure of protected health information by health plans, which include both group health plans sponsored by employers and health insurance issuers. Health plan disclosures for payment or health care operations purposes are subject to the minimum necessary provisions of the Rule, and in general, disclosures for other purposes to third parties such as employers or pharmaceutical companies require a valid authorization from the individual.

The Office for Civil Rights' web site, <http://www.hhs.gov/ocr/hipaa/> offers significant additional information to help covered entities understand and comply with the Privacy Rule. This website contains the full text of the Privacy Rule and other documents, such as updated Guidance containing some 200 frequently asked questions, fact sheets, Sample Business Associate Contract Provisions, and links to other helpful Department websites about other aspects of HIPAA. Particularly, we note that the Guidance includes a section which explains at some length how the minimum necessary provisions limit the disclosure of patient health information. In addition, OCR is developing other materials and videos tailored to specific groups, such as professional providers, institutional providers, health plans and State and local governments.

Page 2 - The Honorable Jim Gerlach

If we can be of further assistance, please do not hesitate to contact me.

Sincerely,



Richard M. Campanelli, J.D.

Director

Office for Civil Rights

cc: Scott Exley

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

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**OFFICE OF THE SECRETARY**

Director

Office for Civil Rights

200 Independence Ave., SW Rm 506F

Washington, DC 20201

April 24, 2003

**RECEIVED  
GOULSTON & STORRS****JUL 10 2003****A.S.G.**

The Honorable Saxby Chambliss  
United States Senator  
6501 Peake Rd, Bldg 950  
Macon, Georgia 31210  
Attn: Ms. Rachel Skilling

Dear Senator Chambliss:

Thank you for your inquiry on behalf of your constituent, Robert T. Shepherd, Ph.D., who expressed concerns regarding the health information privacy regulation (Privacy Rule), issued pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Your letter to the Office of the HHS Assistant Secretary for Legislation was forwarded to the Department's Office for Civil Rights (OCR) for reply. OCR is responsible for implementing and enforcing the Privacy Rule, issued pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Dr. Shepherd expressed confusion as to the requirements of the Privacy Rule and in particular, what forms are required to be sent to HHS. In fact, Dr. Shepherd will be pleased to learn that the Privacy Rule does not require him to file any "form" or other report to this Department. Under the HIPAA Privacy Rule, covered health care providers, which are those providers that electronically conduct certain administrative and financial transactions (such as electronic claims submission), must implement policies and procedures to protect the privacy of patient health information, and provide patients more control over that information. These requirements include:

- Notifying patients about their privacy rights and how their information can be used.
- Adopting and implementing appropriate privacy procedures for its practice.
- Training employees so that they understand the privacy procedures.
- Designating an individual to be responsible for seeing that the privacy procedures are adopted and followed.
- Securing patient records containing individually identifiable health information so that they are not readily available to those who do not need them.

Page 2 - The Honorable Saxby Chambliss

Many health care providers already take the kinds of steps required by the Rule to protect patients' privacy. Further, because entities of all types and sizes must comply with the Privacy Rule, the Rule eases the burden of complying by giving providers and health plans the flexibility needed to create privacy procedures that are tailored to fit their particular circumstances.

The Office for Civil Rights' web site, <http://www.hhs.gov/ocr/hipaa/> offers significant additional information to help covered entities understand and comply with the Privacy Rule. This website contains the full text of the Privacy Rule and other documents, such as updated Guidance containing some 200 frequently asked questions, fact sheets, Sample Business Associate Contract Provisions, and links to other helpful Department websites about other aspects of HIPAA. In addition, OCR is developing other materials tailored to specific groups, such as professional providers, institutional providers, health plans and State and local governments.

We trust this information will be helpful to Dr. Shepherd. If we can be of further assistance, please do not hesitate to contact me.

Sincerely,



Richard M. Campanelli, J.D.

Director

Office for Civil Rights





**DEPARTMENT OF HEALTH & HUMAN SERVICES**  
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**OFFICE OF THE SECRETARY**

Director  
Office for Civil Rights  
200 Independence Ave., SW Rm 506F  
Washington, DC 20201

March 12, 2003

Leslie A. Spry, M.D. F.A.C.P., Jeffery T. Marple, M.D.,  
Gerard P. Hafner, M.D., Timothy C. Govaerts, M.D.  
Lincoln Nephrology and Hypertension, P.C.  
7441 "O" Street, Suite 304  
Lincoln, NE 68510

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GOULSTON & STORRS

JUL 10 2003

**A.S.G.**

Dear Doctors Spry, Marple, Hafner and Govaerts:

Secretary Thompson asked me to thank you for your letter regarding the application of the health information privacy regulation (Privacy Rule) to small physician practices, and to reply directly to you. The Secretary and I appreciate the efforts of health care providers in support of effective and efficient implementation of the Privacy Rule. The Office for Civil Rights (OCR) is responsible for implementing the Privacy Rule.

We are unable to meet your request for a one year extension for compliance with the Privacy Rule. Congress required in the Health Insurance Portability and Accountability Act (HIPAA) that all covered health care providers and most other covered entities be in compliance with the Privacy Rule within two years of the promulgation of the regulation, or April 14, 2003. The statute provides small health plans with an additional year to come into compliance, but does not provide any such provision for small health care providers; it also does not provide for any extensions.

Guidance containing fact sheets and frequently asked questions on several topics can be found at our web site, <http://www.hhs.gov/ocr/hipaa>. The site also provides a broad array of other technical assistance materials developed by OCR and other Department divisions, including:

- The full text of the Privacy Rule
- Sample Business Associate Contract Provisions
- Links to other helpful Department web sites

OCR also is developing other materials tailored to specific groups, such as consumers, professional providers, institutional providers, health plans and State and local governments.

Page 2 - Doctors Spry, Marple, Hafner and Govaert

We trust this information will be useful to you. If you have any further questions, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Campanelli". The signature is fluid and cursive, with a large initial "R" and a long, sweeping tail.

Richard M. Campanelli, J.D.  
Director  
Office for Civil Rights

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200 Independence Ave., SW Rm 506F  
Washington, DC 20201

April 24, 2003

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GOULSTON & STORRS

JUL 10 2003

A.S.G.

Jonathan Chinn, M.D.  
1551 Northwest 54<sup>th</sup> Street, Suite 101  
Seattle, Washington 98107

Dear Dr. Chinn:

Senator Maria Cantwell forwarded to this Department your letter regarding health plan access to your patient records. Your letter then was forwarded to the Department's Office for Civil Rights (OCR) for reply. OCR is responsible for implementing and enforcing the Privacy Rule, issued pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Secretary and I appreciate and share your concern for the confidentiality of patient records.

You raised specific concerns regarding disclosures made to a health plan pursuant to a "practitioner authorization" for credentialing activities. As you may be aware, the protections of the Privacy Rule apply to disclosures of or requests for individually identifiable health information made by a covered health care provider or a health plan. Contracts between covered providers and health plans do not supersede the requirements of the Privacy Rule; nor does the document included in your correspondence purport to do so. In responding to a particular health plan request for information made pursuant to a "practitioner authorization", a covered health care provider would need to analyze whether the disclosure would be permitted by the Privacy Rule. For example, a covered health care provider seeking credentialing by a health plan may disclose protected health information without patient authorization as needed for that activity, because credentialing activities are included in the definition of health care operations, and § 164.506(c)(1) permits such disclosures. The "minimum necessary" provisions apply to these disclosures. A covered health care provider may reasonably rely on the minimum necessary determination of the health plan requesting the information.

On the other hand, we note that a hospital responding to a health plan request for information must also comply with the Privacy Rule; absent a valid authorization signed by the individual, the Privacy Rule does not permit a hospital to disclose protected health information to a health plan seeking it for credentialing of a private physician.

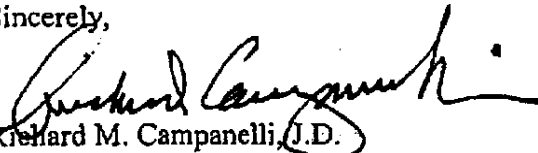
The Office for Civil Rights' web site, <http://www.hhs.gov/ocr/hipaa/> offers significant additional information, including discussions of the minimum necessary provisions, to help covered entities comply with the Privacy Rule. This website contains the full text of the Privacy Rule and other documents that will assist covered entities with their compliance efforts, such as updated Guidance containing fact sheets on pertinent topics, some 200 Frequently Asked Questions, Sample Business Associate Contract Provisions, and links to other helpful Department web sites

Page 2 - Jonathan Chinn, M.D.

about other aspects of HIPAA. In addition, OCR is developing other materials and videos tailored to specific groups, such as professional providers, institutional providers, health plans and State and local governments.

I trust that this information will be of assistance to you.

Sincerely,



Richard M. Campanelli, J.D.

Director

Office for Civil Rights

cc: Carl See, Office of Senator Maria Cantwell

**DEPARTMENT OF HEALTH & HUMAN SERVICES**Voice - (202) 619-0403 TDD - (202) 619-3257 Fax - (202) 619-3818  
Http://www.hhs.gov/ocr/**OFFICE OF THE SECRETARY**Director  
Office for Civil Rights  
200 Independence Ave., SW Rm 506F  
Washington, DC 20201

December 20, 2002

RECEIVED  
GOULSTON & STORRS

JUL 10 2003

**A.S.G.**The Honorable Jim Nussle  
House of Representatives  
Washington, D.C. 20515

Dear Congressman Nussle:

Thank you for your inquiry on behalf of the Tama County Board of Supervisors, which posed several questions regarding implementation of the Health Insurance Portability and Accountability Act (HIPAA). Your letter to Secretary Thompson was forwarded to the Office for Civil Rights (OCR) in the Department of Health and Human Services for reply. OCR is responsible for implementing and enforcing the new health information privacy regulation (Privacy Rule) issued pursuant to HIPAA. The Secretary and I are committed to protecting the privacy of health information through implementation of the Privacy Rule, and the Department is undertaking a broad range of efforts to assist covered entities in voluntarily complying with their obligations under HIPAA.

The Office for Civil Rights makes available information designed to facilitate compliance with the federal privacy rule at our website: <http://www.hhs.gov/ocr/hipaa/>. In addition to containing the full text of the Privacy Rule and associated preambles, the website contains several documents intended to assist covered entities with their compliance efforts, such as updated Guidance containing frequently asked questions and fact sheets, Sample Business Associate Contract Provisions, and links to other relevant websites. The Office for Civil Rights also is developing technical assistance documents and videos tailored to professional providers, institutional providers, health plans and State and local governments. Information about other HIPAA Administrative Simplification requirements is available through the Centers for Medicare and Medicaid Services (CMS) HIPAA website at <http://www.cms.hhs.gov/hipaa/hipaa2/>.

Tama County may also find assistance through other organizations. The National Association of Counties provides information about implementation of the HIPAA Privacy Rule on its website, [www.naco.org](http://www.naco.org). In addition, many Iowa counties are participating in the HIPAA Government Information Value Exchange for States (HIPAA GIVES), which may be a helpful source of information on HIPAA implementation planning. HIPAA GIVES can be reached at [www.HIPAAGIVES.org](http://www.HIPAAGIVES.org). We note that this Department has not reviewed non-Departmental websites and, thus, cannot endorse or certify the material on these sites as accurate.

Page 2 - The Honorable Jim Nussle

Regarding the specific comments made by the supervisors, we believe that the long term economies that will accrue from implementation of the standard electronic transactions adopted through the Transactions Rule exceed the costs of implementation of the Privacy Rule and the other administrative simplification rules. The preamble to the Privacy Rule published December 28, 2000 contains a detailed cost analysis, including a section on costs to State and local governments. See 65 FR 82775 - 82776. Regarding the supervisors' concerns about perceived ambiguity in aspects of the Privacy Rule, please be assured that in crafting the Rule and in its significant technical assistance, the Department is making every effort to assist covered entities in understanding and complying with the Rule; but that in many respects the Privacy Rule was crafted to allow covered entities of various sizes and structures the flexibility to implement these standards using methods and approaches that are appropriate to their specific situations. Thus, we encourage covered entities to carefully review the preambles to the Privacy Rule, which contain a great deal of interpretation and assistance for covered entities, and current and future Department guidance, which will assist entities in applying these standards in a manner appropriate to their particular structures and context.

We trust this information will be helpful to you and to the Tama County Board of Supervisors. If you have any further questions, please do not hesitate to contact me.

Sincerely,



Richard M. Campanelli, J.D.

Director

Office for Civil Rights



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**OFFICE OF THE SECRETARY**

Director  
 Office for Civil Rights  
 200 Independence Ave., SW Rm 506F  
 Washington, DC 20201

JAN 22 2003

The Honorable Virgil Goode  
 Member, U.S. House of Representatives  
 70 East Court St., Suite 215  
 Rocky Mount, VA 24151

RECEIVED  
 GOULSTON & STORRS

JUL 10 2003

**A.S.G.**

Dear Congressman Goode:

Tom Scully, Administrator of the Department's Centers for Medicare and Medicaid Services, has asked me to thank you for your letter and the communication from your constituent, Dr. John H. Knight, DDS, regarding the Department's regulations under the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act (HIPAA) (P.L. 104-191), and to reply directly to you. The Office for Civil Rights (OCR), within the Department, has responsibility for the implementation and enforcement of the HIPAA Privacy Rule, which establishes standards for the privacy of individually identifiable health information. The Department believes strongly in the need for federal protections to ensure patients' privacy.

Your letter expresses concern that the HIPAA regulations have gone beyond the original intent of the legislation and imposes excessive requirements on dental offices. Please let me assure you that the intent of HIPAA is not to impose an excessive burden on the offices of small providers such as Dr. Knight's dental office. The goal of the Administrative Simplification provisions of HIPAA is to reduce the economic and administrative burden on health care providers by establishing mandatory standards for electronic transactions meaning, for example, that all health plans will use the same claims submission transaction format.

It is unclear from Dr. Knight's letter whether his office is a covered entity under HIPAA. Health care providers are covered by HIPAA if they transmit any health information in electronic form in connection with transactions for which the Secretary has adopted standards; the standards are at 45 C.F.R. Part 162. If a health care provider uses another entity (such as a clearinghouse) to conduct covered transactions in electronic form on its behalf, the health care provider is considered to be conducting the transaction in electronic form. One of the covered transactions is the electronic submission of health care claims. If, for example, Dr. Knight's office submits paper claims instead of electronic claims to payers and does not conduct other covered transactions in electronic form, then the office is not covered by HIPAA and is not required to comply with the requirements of the HIPAA Privacy Rule.

If Dr. Knight is a covered provider under HIPAA, then please be assured that the Privacy Rule's requirements are designed to minimize the burden on small providers. As to your concerns about the Rule's requirements for the designation of a privacy officer and the development of an employee discipline process for privacy violations, these requirements are flexible and scalable according to the size and complexity of the covered health care provider. In other words, a small provider can designate the office manager as the privacy officer and have and apply simple

Page 2 - The Honorable Virgil Goode

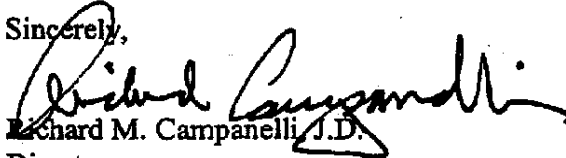
sanctions for office employees who do not comply with privacy policies and procedures. As to your concern about the Rule's requirement for business associate agreements, the Department has developed and published sample business associate contract provisions. These provisions were published in the August 14, 2002 edition of the Federal Register and are posted on the Office for Civil Rights web site at <http://www.hhs.gov/ocr/hipaa/contractprov.html>. Also, OCR is currently developing educational materials, including sample forms, for the use of small providers, and materials and videos tailored to specific groups such as small health care providers.

These efforts are part of the wide range of activities the Department is undertaking to assist covered entities and others in understanding the requirements of the Privacy Rule. All of these materials may be accessed at <http://www.hhs.gov/ocr/hipaa/>. Available on the website are:

- The Department's "Covered Entity Decision Tools," which can assist entities in determining whether they must comply with the Privacy Rule;
- Extensive Guidance, Fact Sheets and Frequently Asked Questions;
- The full text of the Privacy Rule; and
- Links to other helpful Department websites.

We trust this information is helpful to you and your constituent. Should you have any additional questions or concerns, please call me at (202) 619-0403.

Sincerely,



Richard M. Campanelli, J.D.

Director

Office for Civil Rights



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

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Director

Office for Civil Rights

200 Independence Ave., SW Rm 506F

Washington, DC 20201

December 23, 2002

RECEIVED  
GOULSTON & STORRS

JUL 10 2003

A.S.G.

The Honorable Frank H. Murkowski  
United States Senate  
Washington, D.C. 20510

Dear Senator Murkowski:

Thank you for your inquiry on behalf of Pamela Peters of the Fairbanks Cancer Treatment Center, Fairbanks Memorial Hospital, who raised concerns regarding implementation of the Health Insurance Portability and Accountability Act (HIPAA). Your letter to Secretary Thompson was forwarded to the Office for Civil Rights (OCR) in the Department of Health and Human Services for reply. OCR is responsible for implementing and enforcing the health information privacy regulation (Privacy Rule) issued pursuant to HIPAA. The Secretary and I are committed to ensuring the privacy of protected health information. At the same time, the Department is undertaking a broad range of efforts to assist covered entities in voluntarily complying with their obligations under HIPAA.

Ms. Peters is concerned that the Privacy Rule would impede the ability of the center to continue to obtain patient specific information about disease progression and treatment from other health care providers. The information is gathered to study treatment effectiveness and track the nature and behavior of the disease. In general, the Privacy Rule requires covered entities to obtain a patient's authorization in order to make disclosures for purposes unrelated to the patient's care or payment for care. The Privacy Rule does permit disclosure by health care providers and other covered entities of certain protected health information without patient authorization to public health authorities for public health surveillance activities, which would include disclosures of patient information to state cancer registries. For the exemption to apply to a non-governmental registry, however, the registry must operate pursuant to a contract with a public agency or under a grant of authority from a public agency to collect or receive information for public health purposes (see §165.512(b)(i)). However, the public health provision does not otherwise apply to disclosures to private cancer registries, as the Fairbanks Cancer Treatment Center may be.

Covered health care providers may be able to continue disclosing patient information to the Fairbanks Cancer Treatment Center consistent with the Privacy Rule. Disclosures to private cancer registries may be permitted by the Rule through one of three provisions:

Page 2 - The Honorable Frank H. Murkowski

First, a covered entity may disclose protected health information to a private cancer registry if it receives a valid authorization signed by the patient permitting the disclosure. See §164.508.

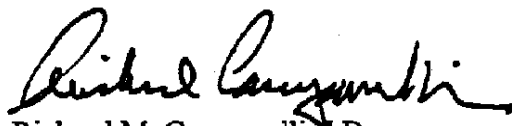
Second, a covered entity may disclose protected health information for research purposes, which includes the creation of databases, consistent with the requirements of §164.512(i). This provision generally permits a covered entity to disclose identifiable patient information to a researcher when the researcher provides documentation that waiver of patient authorization has been approved by an Institutional Review Board or privacy board.

Third, when two covered entities both have a relationship with an individual (e.g., a patient's primary care doctor and the hospital where specialized treatment was obtained) the Rule permits a covered entity to disclose protected health information pertaining to such relationship to the other covered entity for certain activities conducted by the recipient entity. These activities may include quality assessment and improvement activities, population-based activities relating to improving health, and protocol development. See §164.506(c)(4). Please note that this provision does not permit disclosure of information if the primary purpose of the activity is obtaining generalizable knowledge; an individual authorization or appropriate disclosure for research purposes, as described above, would be the appropriate routes for such activities.

We suggest that Ms. Peters explore the applicability of the above provisions to the particular circumstances of the Fairbanks Cancer Treatment Center. The Office for Civil Rights also makes available information designed to facilitate compliance with the Privacy Rule at our website: <http://www.hhs.gov/ocr/hipaa/>. In addition to containing the full text of the Privacy Rule and associated preambles, the website contains several documents intended to assist covered entities with their compliance efforts, such as the Guidance, Frequently Asked Questions, Fact Sheets, Sample Business Associate Contract Provisions, and links to other relevant websites. The Office for Civil Rights also is developing technical assistance documents and other products tailored to professional providers, institutional providers, health plans and State and local governments.

I hope that the above information is helpful to you and Ms. Peters. Please contact me with any further questions or concerns.

Sincerely,



Richard M. Campanelli, J.D.  
Director  
Office for Civil Rights