



Collection of Resources and Sample Forms

TECHNICAL ASSISTANCE IS AVAILABLE!

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**For an electronic copy of this Collection of Resources and Sample Forms, including the
“hot links” and formatted forms, please call or e-mail for Technical Assistance!**

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RESOURCES AND LINKS FOR MORE INFORMATION

RESOURCES RELATED TO PRIVACY, CONFIDENTIALITY & ETHICS:

The Federal AOD Confidentiality Rule, 42 C.F.R. Part 2:

http://www.access.gpo.gov/nara/C.F.R./waisidx_99/42C.F.R.v1_99.html, or
http://www.access.gpo.gov/nara/cfr/waisidx_04/42cfrv1_04.html

Click on Part 2 for a full collection of the 42 C.F.R. Part 2 regulations entitled “Confidentiality of alcohol and drug abuse patient records”.

The HIPAA Privacy Rule, 45 C.F.R. Parts 160 & 164:

<http://www.hhs.gov/ocr/combinedregtext.pdf>

Although this document is marked “unofficial version,” this is the complete privacy, security and enforcement (procedural) regulation text. The Office of the Federal Register publishes the official version of all Federal regulations in the Code of Federal Regulations (C.F.R.).

The Confidentiality of Alcohol and Drug Abuse Patient Records Regulation and the HIPAA Privacy Rule: Implications for Alcohol and Substance Abuse Programs

This document compares the Confidentiality of Alcohol and Drug Abuse Patient Records regulation (42 CFR Part 2) with the HIPAA Privacy Rule (45 CFR Parts 160 and 164). The comparison document is a summary that highlights the most significant areas in which the two federal regulations interact. It is targeted to programs that already comply with the "Part 2" regulations but require direction on how to integrate the Privacy Rule into their business and clinical processes. On or about May 28, 2004, this document was officially cleared by the U.S. Department of Health and Human Services. It is posted to the SAMHSA HIPAA website at <http://www.hipaa.samhsa.gov/privacyrule.htm>. This publication can be ordered through SAMHSA’s National Clearinghouse for Alcohol and Drug Information (NCADI) at www.health.org or <http://ncadi.samhsa.gov>, using the NCADI Inventory Number PHD1083, or by calling the Toll Free Number: 1-800-729-6686.

The Office for Civil Rights’ HIPAA Web Site

<http://www.hhs.gov/ocr/hipaa/>

OCR is responsible for the implementation and enforcement of HIPAA regulations within the Department of Health and Human Services (HHS). This Web site has a wealth of HIPAA-related information and links. Within this site, or at <http://www.hhs.gov/ocr/hipaa/assist.html>, you will find, among many other useful materials, a New OCR Summary of HIPAA Privacy Rule posted [RTF] | [PDF]; [View and Search Health Information Privacy Frequently Asked Questions \(FAQs\)](#) [this a very large, searchable database of FAQs]; [How to File a Health Information Privacy Complaint with the Office for Civil Rights](#); [OCR Guidance Explaining Significant Aspects of the Privacy Rule](#) - December 4, 2002, Revised April 3, 2003 - where you

can search and or copy the complete guidance document ([PDF - 165KB](#)) ([WP - 233KB](#)) ([RTF - 300KB](#)), or the following individual sections:

- Introduction ([PDF](#)) ([WP](#)) ([RTF](#))
- General Overview ([PDF](#)) ([WP](#)) ([RTF](#))
- Incidental Uses and Disclosures ([PDF](#)) ([WP](#)) ([RTF](#))
- Minimum Necessary ([PDF](#)) ([WP](#)) ([RTF](#))
- Personal Representatives ([PDF](#)) ([WP](#)) ([RTF](#))
- Business Associates ([PDF](#)) ([WP](#)) ([RTF](#))
- Uses/Disclosures for Treatment, Payment, & Health Care Operations ([PDF](#))([WP](#)) ([RTF](#))
- Marketing ([PDF](#)) ([WP](#)) ([RTF](#))
- Public Health ([PDF](#)) ([WP](#)) ([RTF](#))
- Research ([PDF](#)) ([WP](#)) ([RTF](#))
- Workers' Compensation Laws ([PDF](#)) ([WP](#)) ([RTF](#))
- Notice ([PDF](#)) ([WP](#)) ([RTF](#))
- Government Access ([PDF](#)) ([WP](#)) ([RTF](#))

**Substance Abuse and Mental Health Services Administration's (SAMHSA's)
HIPAA Web site:**

<http://www.samhsa.gov> (and go to Quick Picks, HIPAA)

SAMHSA's HIPAA Web site contains many useful links to tools and materials regarding privacy, electronic transactions, and security.

**The Office for Civil Rights' HIPAA Privacy Call Center ("HIPAA Hotline")
Toll Free Number: 1-866-627-7748**

This call center was set up by the Office for Civil Rights (OCR) to provide information and answer questions about the HIPAA. An automatic call center provides prompts to valuable information about various standards with respect to HIPAA, and a customer service representative can be requested where further information is needed.

**SAMHSA/CSAT's Confidentiality & Ethics Training Call Center
Toll Free Number: 1-866-447-2284**

As part of SAMHSA/CSAT's Confidentiality & Ethics Training (CET) Project, individualized technical assistance is available through its call center and e-mail service to all CET project trainees and those within their programs, with regard to questions pertaining to confidentiality and privacy issues, as well as questions regarding HIPAA's electronic and security standards. See CET training manual for appropriate staff e-mail addresses.

HIPAA Consumer Fact Sheets:

ORC has three Fact Sheets which provide an easy-to-understand overview of what the Privacy Rule means to consumers. They can be readily accessed from the "For Consumers" column on the OCR website, <http://www.hhs.gov/ocr/hipaa/>. The first Fact Sheet, entitled, "Privacy and

Your Health Information" is a general overview of the Rule, explaining that the Privacy Rule gives individuals rights over their health information, sets rules and limits on how information can be used and disclosed, and requires covered entities to take steps to protect health information. The second Fact Sheet, entitled, "Your Health Information Privacy Rights," focuses on each of the privacy rights individuals have under the Privacy Rule. The third Fact Sheet is entitled "Protecting the Privacy of Patients' Health Information" which provides a clear overview of the new HIPAA privacy regulations for consumers.

SAMHSA's National Clearinghouse for Alcohol and Drug Information (NCADI)

www.health.org or <http://ncadi.samhsa.gov>

Toll Free Number: 1-800-729-6686

The following Technical Assistance Publications (TAPs) and Treatment Improvement Protocol (TIPs) contain information regarding the Alcohol and Other Drug (AOD) Confidentiality Rule in 42 C.F.R. Part 2. [Note that these TAPs/TIPs do not address, and were published prior to, the HIPAA privacy provisions. They are, however, still relevant and pertinent to the application of the 42 CFR Part 2 regulations.] Web links are provided for the publications listed below that are available online. All listed publications are free and can be ordered by clicking the NCADI link at http://store.health.org/catalog/SC_Itemlist.aspx and using the NCADI Inventory Number listed below each respective publication.

Technical Assistance Publications (TAPs):

TAP 11: Treatment for Alcohol and Other Drug Abuse, Opportunities for Coordination
Chapter 11—Confidentiality
NCADI Inventory Number: PHD663
<http://sad.health.org/pub/AD29467.pdf>

TAP 13: Confidentiality of Patient Records for Alcohol and Other Drug Treatment
Chapter 1—Overview of the Federal Alcohol and Other Drug
Confidentiality Law and Regulations
Chapter 2—Confidentiality of Alcohol and Other Drug Treatment
Records and Communicable Disease: Options for Successful
Communication and Collaboration
NCADI Inventory Number: BKD156
<http://sad.health.org/pub/AD33026.pdf>

TAP 18: Checklist for Monitoring Alcohol and Other Drug Confidentiality
Compliance
Includes within Appendix B an article entitled
"Managed Care and Client Confidentiality"
NCADI Inventory Number: PHD722
<http://sad.health.org/pub/AD41421.pdf>
www.treatment.org/TAPS/TAP18/TAP18.html

- TAP 21: Addiction Counseling Competencies: The Knowledge, Skills, and Attitudes of Professional Practice
 Section 2, VIII, entitled “Professional and Ethical Responsibilities”
 Currently Under Revision
 NCADI Inventory Number: BKD246
www.treatment.org/taps/tap21/TAP21Toc.html
<http://sad.health.org/pub/AD48049.pdf>
- TAP 22: Contracting for Managed Substance Abuse and Mental Health Services: A Guide for Public Purchasers
 Chapter V—The Management Information System, Subsection E entitled “Confidentiality Considerations”
 Chapter VIII—Consumer Protections, Section A regarding Managed Care Consumers’ Rights, Subsection 2 entitled “Confidentiality”
 NCADI Inventory Number: BKD252
www.treatment.org/taps/tap22/TAP22TOC.htm
- TAP 24: Welfare Reform and Substance Abuse Treatment Confidentiality: General Guidance for Reconciling Need to Know and Privacy
 NCADI Inventory Number: BKD336
www.treatment.org/Taps/Tap24.pdf
- TAP 26: Identifying Substance Abuse Among TANF-Eligible Families
 Appendix F, Sample Consent/Confidentiality Forms
 NCADI Inventory Number: BKD410
- TAP 27: Navigating the Pathways: Lessons and Promising Practices in Linking Alcohol and Drug Services With Child Welfare
 Chapter XII, Lessons from the Case Studies, Section regarding “Information Sharing and Data Systems”, entitled “Confidentiality”
 NCADI Inventory Number: BKD436

Treatment Improvement Protocol (TIPs):

- TIP 3: Screening and Assessment of Alcohol - and Other Drug – Abusing Adolescents (Being replaced by TIP31)
 -- Chapter 4—Legal Issues in the Screening and Assessment of Adolescents
<http://sad.health.org/pub/AD15141.pdf>
- TIP 5: Improving Treatment for Drug-Exposed Infants
 Chapter 5—Ethical and Legal Guidelines
 Chapter 6—Quality Assurance Guidelines
 NCADI Inventory Number: BKD110
<http://sad.health.org/pub/AD19307.pdf>
www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.24127

- TIP 6: Screening for Infectious Diseases Among Substance Abusers
Chapter 3—Legal and Ethical Issues
NCADI Inventory Number: BKD131
www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.25461
- TIP 7: Screening and Assessment for Alcohol and Other Drug Abuse Among Adults in the Criminal Justice System
(Being replaced by TIP 44)
-- Chapter 3—Screening, Assessment, and Readiness for Treatment, section entitled “Confidentiality and Client Consent”
-- Chapter 6—Legal and Ethical Issues
<http://sad.health.org/pub/AD31156.pdf>
- TIP 8: Intensive Outpatient Treatment for Alcohol and Other Drug Abuse
Chapter 7—Legal Issues for IOT Programs
NCADI Inventory Number: BKD139
<http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?CMD=search&DB=books> (Type in the title able in black after Search books for)
- TIP 11: Simple Screening Instruments for Outreach for Alcohol And Other Drug Abuse And Infectious Diseases
Chapter 5—Legal Issues Surrounding Client Confidentiality
NCADI Inventory Number: BKD143
www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.32939
- TIP 13: The Role and Current Status of Patient Placement Criteria in The Treatment of Substance Use Disorders
Chapter 7—Ethical and Legal Issues
NCADI Inventory Number: BKD161
<http://sad.health.org/pub/AD34559.pdf>
- TIP 17: Planning for Alcohol And Other Drug Abuse Treatment for Adults in the Criminal Justice System
(Being replaced by TIP 44)
-- Chapter 8—Confidentiality Issues
<http://sad.health.org/pub/AD36451.pdf>
- TIP 18: The Tuberculosis Epidemic: Legal and Ethical Issues for Alcohol and Other Drug Abuse Treatment Providers
Chapter 4—AOD Programs and Public Health: Joining Together To Fight the Spread of TB
Appendix C—Sample Forms
NCADI Inventory Number: BKD173
<http://sad.health.org/pub/AD37443.pdf>
www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.38602

- TIP 19: Detoxification From Alcohol And Other Drugs
Appendix E—Legal and Ethical Issues for Detoxification Programs
NCADI Inventory Number: BKD1172
<http://sad.health.org/pub/AD37217.pdf>
www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.39784
- TIP 23: Treatment Drug Courts: Integrating Substance Abuse With Legal Case Processing
Chapter 8—Legal and Ethical Issues
NCADI Inventory Number: BKD205
<http://sad.health.org/pub/AD41859.pdf>
www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.44270
- TIP 24: A Guide to Substance Abuse Services for Primary Care Clinicians
Chapter 5—Specialized Substance Abuse Treatment Programs, section entitled “Confidentiality”
Appendix B—Legal and Ethical Issues
NCADI Inventory Number: BKD234
<http://sad.health.org/pub/AD46267.pdf>
www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.45293
- TIP 25: Substance Abuse Treatment and Domestic Violence
Chapter 5—Legal Issues, section entitled “Other Legal Issues”
NCADI Inventory Number: BKD239
www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.46712
- TIP 26: Substance Abuse Among Older Adults
Appendix A—Legal and Ethical Issues
NCADI Inventory Number: BKD250
<http://sad.health.org/pub/AD48053.pdf>
www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.48302
- TIP 30: Continuity of Offender Treatment For Substance Use Disorders From Institution to Community
Chapter 4—Administrative Guidelines, section entitled “Confidentiality Issues”
NCADI Inventory Number: BKD304
<http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.53792>
- TIP 31: Screening and Assessing Adolescents for Substance Use Disorders
(Replaces TIP 3)
Chapter 4—Legal Issues in the Screening and Assessment of Adolescents
NCADI Inventory Number: BKD306
<http://sad.health.org/pub/AD51478.pdf>
www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.54841

- TIP 32: Treatment of Adolescents With Substance Use Disorders
(Replaces TIP 3)
Chapter 8—Legal and Ethical Issues
NCADI Inventory Number: BKD307
<http://sad.health.org/pub/AD51482.pdf>
www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.56031
- TIP 36: Substance Abuse Treatment for Persons With Child Abuse and Neglect Issues
Chapter 6—Legal Responsibilities and Recourse
Appendix B—Protecting Clients’ Privacy
NCADI Inventory Number: BKD343
www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.63145
- TIP 37: Substance Abuse Treatment for Persons With HIV/AIDS
Chapter 8—Ethical Issues
Chapter 9—Legal Issues
NCADI Inventory Number: BKD359
www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.64746
- TIP 38: Integrating Substance Abuse Treatment and Vocational Services
Chapter 7—Legal Issues
NCADI Inventory Number: BKD381
www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.68228
- TIP 40 Use of Buprenorphine in the Treatment of Opioid Addiction
Chapter 6—Policies and Procedures
Section entitled “Confidentiality and Privacy”
NCADI Inventory Number: BKD500
<http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.72248>
- TIP 41 Substance Abuse Treatment: Group Therapy
Chapter 4—Group Development and Phase Specific Tasks
Section entitled “Confidentiality”
Chapter 6—Group Leadership, Concepts, and Techniques
Section entitled “Confidentiality”
Chapter 7—Training and Supervision
Section entitled “Legal Issues”
NCADI Inventory Number: BKD507
<http://media.shs.net/prevline/pdfs/bkd507.pdf>
- TIP 42: Substance Abuse Treatment for Persons with Co-Occurring Disorders
(Replaces TIP 9)
Appendix K—Confidentiality
NCADI Inventory Number: BKD515
<http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?CMD=search&DB=Books> (Type in the title able in black after Search books for . . .)

TIP 43: Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs

(Replaces TIP 1, TIP 10, TIP 20 and TIP 22)

Appendix D—Ethical Considerations in MAT

NCADI Inventory Number: BKD524

ncadi.samhsa.gov/media/Prevline/pdfs/bkd524.pdf

TIP 44: Substance Abuse Treatment for Adults in the Criminal Justice System

(Replaces TIP 7, TIP 12 and TIP 17)

Chapter 8—Treatment Issues Specific to Jail’s

Section entitled “Confidentiality” and

Section entitled “Promote Understanding of Institutional Security Rules and Confidentiality Requirements”

Chapter 10—Treatment for Offenders Under Community Supervision

Section Entitled “Information-Sharing and Confidentiality Issues”

NCADI Inventory Number: BKD526

ncadi.samhsa.gov/media/Prevline/pdfs/bkd526.pdf

Federal Confidentiality Laws and How They Affect Drug Court Practitioners

Judge Jeffrey Tauber, Director, et al. (National Drug Court Institute), April, 1999.

<http://www.ndci.org/admin/docs/confid.pdf>

Practical Guide to Applying Federal Confidentiality Laws to Drug Court Operations

<http://spa.american.edu/justice/publications/Confidentiality.pdf>

Center for the Study of Ethics in Professions

Illinois Institute of Technology

<http://ethics.iit.edu/codes/index.html>

This Web site includes a compilation of ethical standards and principles for a variety of different professions in the healthcare field.

U.S. Department of Health and Human Services (HHS)

<http://www.hhs.gov>

This is the HHS homepage. If you search “HIPAA”, you will obtain a variety of HIPAA-related links and materials.

The HIPAA Privacy Rule and Research

<http://privacyruleandresearch.nih.gov/>

This Web site has been developed to provide the research community with information about the HIPAA Privacy Rule and how it might affect research. *Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule*, a booklet discussing how provisions of the privacy rule may affect research, is now available. Additional companion pieces to the

booklet that will address the possible effects of the privacy rule on specific types of research activities are under development and will be available soon through this Web site.

**Health Privacy Project, Institute for Health Care Research and Policy,
Georgetown University**
<http://www.healthprivacy.org/>

Within this Web site is a link to State law, which compiles a summary of existing confidentiality and privacy laws within each State and includes relevant citations. This Web site also includes a summary of the HIPAA Privacy Rule. Recently, this Web site also added a document entitled "Myths and Facts About the HIPAA Privacy Rule", which can be found at http://www.healthprivacy.org/info-url_nocat2303/info-url_nocat_show.htm?doc_id=173435.

Certificates of Confidentiality for Health Research Projects
<http://grants.nih.gov/grants/policy/coc/index.htm>

**OTHER RESOURCES RELATED TO HIPAA TRANSACTION,
CODESET & IDENTIFIER (TCI) STANDARDS:**

All health care providers can apply for their National Provider Identifier (NPI)!

Starting May 23, 2005, all health care providers can apply for their National Provider Identifier (NPI). The NPI will replace health care provider identifiers in use today in standard health care transactions. The health plans with whom you do business will instruct you as to when you may begin using the NPI in standard transactions. All HIPAA covered entities except small health plans must begin using the NPI on May 23, 2007; small health plans have until May 23, 2008. For additional information, and to complete an application, visit <https://nppes.cms.hhs.gov> on the web.

Also, an instructional web tool, called the NPI Viewlet, is now available for viewing at <http://www.cms.hhs.gov/medlearn/npi/npiviewlet.asp> and under "HIPAA Latest News" at www.cms.hhs.gov/hipaa/hipaa2 on the CMS website. This tool provides an overview of the NPI, a walkthrough of the application, as well as live links to the NPPES website where the learner can apply for an NPI. This tool is designed for all health care providers. In the near future, you will also be able to access the viewlet at <https://nppes.cms.hhs.gov> on the web.

Centers for Medicare and Medicaid Services (CMS) HIPAA Home Site
<http://www.cms.hhs.gov/hipaa/hipaa2/default.asp>

Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services (HHS)
<http://aspe.hhs.gov/admsimp/>

WEDI Strategic National Implementation Process (SNIP)

<http://snip.wedi.org>

This Web site is the Workgroup for Electronic Data Interchange (WEDI) Strategic National Implementation Process (SNIP) home page, providing links to several good HIPAA resources.

Implementing the HIPAA Regulations: A Readiness Workshop for the Small/Rural Provider

<http://www.wedi.org/snip/public/articles/WhoWhatWhenAboutHIPAA.ppt>

This PowerPoint presentation, published by the Workgroup for Electronic Data Interchange (WEDI) and CMS, provides guidance on the implementation of TCI standards. This is a big file and may require a few minutes to download.

CAQH-WEDI Health Plan Transaction Status

<http://www.wedi.org/snip/public/articles/index.cfm?fuseaction=archive&owner=snip>

This Web site, created by the Council for Affordable Quality Healthcare (CAQH) and the Workgroup for Electronic Data Interchange (WEDI), is a resource for information on health plan electronic in transaction.

Physician Practice Management System Directory

<http://www.hipaa.org/pmsdirectory>

HIPAA LISTSERVS & INSTRUCTIONS TO SUBSCRIBE

OCR's HIPAA Listserv:

The HHS Office for Civil Rights (OCR), which is responsible for implementation of the HIPAA Privacy Rule, has announced the creation of a listserv to distribute announcements, notices of available resources, and other educational information about the HIPAA Privacy Rule.

To subscribe, please follow the attached link, or cut and paste the following URL address into your browser window: <http://list.nih.gov/cgi-bin/wa?SUBED1=ocr-privacy-list>, or you may go to go to <http://list.nih.gov/> and under browse, select OCR-PRIVACY-LIST. These instructions can also be found on the OCR website at <http://www.hhs.gov/ocr/hipaa/listserv.html>.

SAMHSA's HIPAA Listserv:

SAMHSA also has a HIPAA listserv. Follow the steps below to subscribe to the SAMHSA HIPAA Listserv:

1. Email a message from the e-mail account you wish to receive listserv messages to majordomo@new-bold.com.
2. In the body of the message, type: subscribe samhsa-hipaa.
3. New subscribers will receive a return e-mail with an authorization code. Reply to majordomo@new-bold.com with that code in the body of the message. Do not include any extra characters before or after that particular line of text.

If you have any questions or problems, please call for Technical Assistance and, if necessary, we will put you in touch with SAMHSA's listserv coordinator to address any technical problems or issues in this regard.

AOD SAMPLE FORMS

The forms in this subsection only take into account the Federal Alcohol and Other Drug (AOD) Confidentiality Rule within 42 C.F.R. Part 2.

**CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE
PATIENT RECORDS**

(42 C.F.R. § 2.22(d))

The confidentiality of alcohol and drug abuse patient records maintained by this program is protected by Federal law and regulations. Generally, the program may not say to a person outside the program that a patient attends the program, or disclose information identifying a patient as an alcohol or drug abuser, unless:

- (1) The patient consents in writing;
- (2) The disclosure is allowed by a court order; or
- (3) The disclosure is made to medical personnel in a medical emergency or to qualified personnel for research, audit, or program evaluation.

Violation of the Federal law and regulations by a program is a crime. Suspected violations may be reported to appropriate authorities in accordance with Federal regulations.

Federal law and regulations do not protect any information about a crime committed by a patient either at the program or against any person who works for the program or about any threat to commit such a crime.

Federal laws and regulations do not protect any information about suspected child abuse or neglect from being reported under State law to appropriate State or local authorities.

(See 42 U.S.C. 290dd-3 and 42 U.S.C. 290ee-3 for Federal laws and 42 CFR part 2 for Federal regulations.)

Source:

This sample form is set forth in the federal regulations at 42 C.F.R. § 2.22(d).

CONSENT FOR THE RELEASE OF CONFIDENTIAL ALCOHOL OR DRUG TREATMENT INFORMATION

I, _____, authorize
(Name of patient)

(Name or general designation of program making disclosure)

to disclose to _____ the
(Name of person or organization to which disclosure is to be made)

following information: _____
(Nature of the information, as limited as possible)

The purpose of the disclosure authorized herein is to: _____
(Specific purpose of disclosure)

I understand that my records are protected under the federal regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 CFR Part 2, and cannot be disclosed without my written consent unless otherwise provided for in the regulations. I also understand that I may revoke this consent at any time except to the extent that action has been taken in reliance on it, and that in any event this consent expires automatically as follows:

(Specification of the date, event, or condition upon which this consent expires)

Dated: _____

Signature of patient

Signature of parent, guardian or authorized representative when required

Source: This sample form is set forth in CSAT/SAMHSA's TAP 13, Page 17; TIP 7, Page 41.

**CONSENT FOR THE RELEASE OF CONFIDENTIAL ALCOHOL OR
DRUG TREATMENT AND [TB] [STD] [HIV/AIDS] INFORMATION
TO COMPLY WITH DISEASE REPORTING REQUIREMENTS**

I, _____, authorize
(Name of patient)

_____ ,
The ABC Substance Abuse Program
(Name or general designation of program making disclosure)

to disclose to the [State and/or local] Department of Health officials authorized to require and
(Name of person or organization to which disclosure is to be made)

_____ *receive mandated [HIV/AIDS/STD/TB] reports* _____

the following information: (Nature of the information, as limited possible)

(1) *information that State law requires to be reported about my diagnosis and treatment for—*

(initial any which apply):

- _____ *HIV infection*
- _____ *AIDS*
- _____ *STD (sexually transmitted disease)*
- _____ *TB (tuberculosis)*

(2) *My name and other personal identifying information, if required to be reported by State law; and*

(3) *Information about my status as a patient in alcohol or drug treatment, if required to be reported by State law.*

The purpose of the disclosure authorized herein is to: *allow my alcohol or drug treatment*
(Specific purpose of disclosure)

program (named above) to comply with State law(s) requiring the reporting of cases of

[HIV/AIDS/STD/TB].

I understand that my records are protected under the Federal regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2, and cannot be disclosed without my written consent unless otherwise provided for in the regulations. I also understand that HIV-related information about me, STD-related information about me, and TB-related information about me is protected by State law and cannot be disclosed unless the

disclosure is authorized by State law. I also understand that I may revoke this consent at any time except to the extent that action has been taken in reliance on it, and that in any event this consent expires automatically as follows:

(Specify date, event, or condition upon which this consent expires)

Dated: _____

Signature of patient

Source:

This sample form is set forth in CSAT/SAMHSA's TAP 13, Page 19.

**CONSENT FOR THE RELEASE OF CONFIDENTIAL ALCOHOL OR
DRUG TREATMENT AND [TB] [STD] [HIV/AIDS] CARE**

I, [name and address of patient, authorize –

(1) the following alcohol or drug treatment program(s): [name and address of each treatment program authorized to make and receive disclosures],

AND

(2) the following health care provider(s): [name and address of each [TB] [STD] [and/or] [HIV/AIDS] care provider authorized to make and receive disclosures],

AND

(3) [designate staff of the State/local Department of Health responsible for [TB] [STD] [and/or] [HIV/AIDS] prevention, control and care; specify appropriate name and address] --

to communicate with and disclose to one another the following information:

[Initial each category that applies]*

* _____ (1) Alcohol or drug treatment: information about my participation and attendance in the alcohol or drug treatment program(s) named above that is needed to enable the persons and agencies listed above to provide, coordinate and monitor my treatment for [TB] [STD] [and/or][HIV/AIDS].

* _____ (2) Tuberculosis (TB): information about my diagnosis and treatment for TB that is needed to enable the persons and agencies listed above to provide, coordinate and monitor my treatment for [TB] [STD] [and/or][HIV/AIDS].

* _____ (3) Sexually transmitted disease(s) (STD): information about my diagnosis and treatment for any STD that is needed in order to enable the persons named above to provide, coordinate and monitor my treatment for the [TB] [STD] [and/or] [HIV/AIDS].

* _____ (4) HIV/AIDS: information about my HIV status (including HIV test results and information about my diagnosis and treatment for HIV-related conditions, including AIDS)that is needed to enable the persons and agencies listed above to provide, coordinate and monitor my treatment for [TB] [STD] [and/or][HIV/AIDS].

The purpose of these disclosures is to (1) enable the persons and agencies listed above to provide, coordinate and monitor the treatment I receive for [TB] [STD] [and/or][HIV/AIDS]; and (2) discuss with me any [sexual/needle sharing] partners or contacts and/or family members who might be infected with [TB] [STD] [and/or][HIV/AIDS] and need treatment.

I understand that my alcohol and drug treatment records are protected under the federal regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2, and cannot be disclosed without my written consent unless otherwise provided for in the regulations. I also understand that HIV-related information about me, STD-related information about me, and TB-related information about me is protected by State law, and cannot be disclosed unless the disclosure is authorized by State law.

I understand that I may revoke this consent at any time except to the extent that action has been taken in reliance on it, and that in any event this consent expires automatically as follows:

[Specify date, event, or condition upon which this consent expires. This could be one of the following:

- (1) The date on which my treatment for [TB] [STD] is completed.
- (2) A specific date [such as six months to one year after the consent form is signed.]

Dated: _____

Signature of patient

Source:

This sample form is set forth in CSAT/SAMHSA's TAP 13, Page 20.

MULTIPARTY CONSENT FORM

I, _____, authorize
(Name of patient)

(Name or general designation of program making disclosure)

to disclose to: (the following persons or organizations)

1. _____
2. _____
3. _____

[Consider adding:
the following information: _____
(Nature of the information, as limited as possible)]

The purpose of the disclosure authorized herein is to: **permit the participants of a case conference concerning my case to exchange information with one another.**

I understand that my records are protected under the Federal regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2, and cannot be disclosed without my written consent unless otherwise provided for in the regulations. I also understand that I may revoke this consent at any time except to the extent that action has been taken in reliance on it, and that in any event this consent expires automatically as follows:

(Specify the date, event, or condition upon which this consent expires)

(Date)

(Signature of participant)

(Signature of parent, guardian, or authorized representative, if required)

Source:
This sample form is set forth in CSAT/SAMHSA's TAP 24, Appendix B-3. Bracketed considerations were inserted by Social and Health Services, Ltd., a division of ORC Macro, in order to strictly meet all required elements of a written consent set forth in 42 CFR 2.31.

**CONSENT FOR THE RELEASE OF CONFIDENTIAL INFORMATION:
CRIMINAL JUSTICE SYSTEM REFERRAL**

I, _____, hereby consent to communication between
(Name of Defendant)

_____ and _____
(Treatment Program) (Court, probation, parole, and/or other referring agency)

the following information: _____
(Nature of the information, as limited as possible)

The purpose of and need for the disclosure is to inform the criminal justice agencies listed above of my attendance and progress in treatment. The extent of information to be disclosed is my diagnosis, information about my attendance or lack of attendance at treatment sessions, my cooperation with the treatment program, prognosis, and

I understand that this consent will remain in effect and cannot be revoked by me until:

_____ There has been a formal and effective termination or revocation of my release from confinement, probation, or parole, or other proceeding under which I was mandated into treatment, or

_____ _____
(Other time when consent can be revoked and/or expire)

I also understand that any disclosure made is bound by Part 2 of Title 42 of the Code of Federal Regulations governing confidentiality of alcohol and drug abuse patient records and that recipients of this information may re-disclose it only in connection with their official duties.

(Date)

(Signature of defendant/patient)

(Signature of parent, guardian, or authorized representative if required)

Source: This sample form is set forth in CSAT/SAMHSA's TIP17, Page 76; TIP 7, Page 40; and TIP 23, Page 50.

**CONSENT FOR THE DISCLOSURE OF CONFIDENTIAL SUBSTANCE
ABUSE INFORMATION: DRUG COURT REFERRAL**

I, _____, hereby consent to communication between
(name of defendant)

_____, and Judge _____,
(name of treatment program) (name of presiding judge, drug court judge)

(prosecuting attorney, public defender or defense counsel, and any assistant counsel)

the probation department of _____ and _____.
(name of jurisdiction) (other agency names)

The purpose of, and need for, this disclosure is to inform the court and all other named parties of my eligibility and/or acceptability for substance abuse treatment services and my treatment attendance, prognosis, compliance and progress in accordance with drug court program's monitoring criteria. [*Consider adding:* The type and extent of the information to be disclosed will include only that information which is necessary for, and pertinent to, the drug court program's monitoring criteria in connection with the case/charges noted below.]

Disclosure of this confidential information may be made only as necessary for, and pertinent to, hearings and/or reports concerning:

(List charges, docket number, and indictment number)

[*Consider adding:* I understand that such information, where necessary, will be disclosed in open-court, which is a public forum, and I hereby authorize the same.

I understand that this consent will remain in effect and cannot be revoked by me until there has been a formal and effective termination of my involvement with the drug court program for the above-references case, such as the discontinuation of all court _____
supervision upon my successful completion of the
(and/or, where relevant, probation)

drug court requirements OR upon sentencing for violating the terms of my drug court involvement _____.
(and/or, where relevant, probation)

I understand that my disclosure made is bound by Part 2 of Title 42 of the code of Federal Regulations, which governs the confidentiality of substance abuse patient records and that recipients of this information may redisclose it only in connection with their official duties.

Date

Name

Signature

Signature of Defense Counsel

Signature of Interpreter (if applicable)

Signature of parent or guardian (if applicable)

Source:

This form is modeled after the form adopted by the National Drug Court Institute in its publication entitled "Federal Confidentiality Laws and How They Affect Drug Court Practitioners", April 1999. A version of this form is also set forth in a publication by the U.S. Department of Justice, Office of Justice Programs, Drug Courts Program Office, entitled "Practical Guide for Applying Federal Confidentiality Laws to Drug Court Operations". Bracketed considerations were inserted by Social and Health Services, Ltd., a division of ORC Macro.

REQUIRED NOTICE PROHIBITING REDISCLOSURE THAT NEEDS TO ACCOMPANY DISCLOSURES MADE WITH PATIENT CONSENT

(42 C.F.R. § 2.32)

This notice accompanies a disclosure of information concerning a client in alcohol/drug abuse treatment, made to you with the consent of such client. This information has been disclosed to you from records protected by Federal confidentiality rules (42 C.F.R. Part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 C.F.R. Part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

Source:

This sample form is set forth in the federal regulations at 42 C.F.R. § 2.32 and in CSAT/SAMHSA's TAP 13, Page 18.

Another, similar form used, is as follows:

**Prohibition on Redisclosure of Information
Concerning Client in Alcohol or Drug Abuse Treatment**

This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR Part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR Part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

Source:

This sample form is set forth in CSAT/SAMHSA's TAP 24, Appendix B-4 (Sample Form #3).

QUALIFIED SERVICE ORGANIZATION AGREEMENT

_____ and
(Name of Outside Service Organization)

_____ (“the Program”)
(Name of treatment program)

hereby enter into a qualified service organization agreement (QSOA), whereby

_____ agrees to provide
(Name of Service Organization)

(Nature of services to be provided.)

Furthermore, _____:
(Name of Outside Service Organization)

(1) acknowledges that in receiving, storing, processing and otherwise dealing with any information from the Program about the patients in the Program, it is fully bound by the provisions of the Federal regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2; and

(2) undertakes to resist in judicial proceedings any effort to obtain access to information pertaining to patients otherwise than as expressly provided for in the Federal confidentiality regulations, 42 C.F.R. Part 2.

Executed this _____ day of _____, _____.

President of Outside Service Organization
[Name of Outside Service Organization]
[address]

Program Director
[Name of the Program]
[address]

Source:

This sample form is modeled after CSAT/SAMHSA's TAP 24, Appendix B-5.

**QUALIFIED SERVICE ORGANIZATION AGREEMENT ON
COORDINATION OF [HIV/STD/TB] CARE**

(AOD TREATMENT PROGRAM & HIV/STD/TB HEALTH CARE PROVIDER)

[Name of health care facility providing [HIV / AIDS / STD / TB] care to Program patients] (“the [HIV / AIDS / STD / TB] Care Provider”) and the [name of alcohol or drug treatment program] (“the Program”) hereby enter into a qualified service organization agreement, whereby the [HIV / AIDS / STD / TB] Care Provider agrees to [provide, coordinate and/or monitor] the treatment and / or related services for [HIV / AIDS / STD / TB] being provided to patients of the Program who are diagnosed, treated and/or provided related services for [HIV / AIDS / STD / TB] by the [HIV / AIDS / STD / TB] Care Provider.

Furthermore, the [HIV / AIDS / STD / TB] Care Provider:

(1) acknowledges that in receiving, storing, processing or otherwise dealing with any information from the Program about the patients in the Program, it is fully bound by the provisions of the federal regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2; and

(2) undertakes to resist in judicial proceedings any effort to obtain access to information pertaining to patients otherwise than as expressly provided for in the Federal confidentiality regulations, 42 C.F.R. Part 2.

Executed this _____ day of _____, 200__.

President
[Name of [HIV / AIDS / STD / TB] Care Provider]
[address]

AOD Program Director
[Name of Program]
[address]

Source:

This sample form is set forth in CSAT/SAMHSA’s TAP 13, Page 21.

**QUALIFIED SERVICE ORGANIZATION AGREEMENT
ON REPORTING OF [HIV / AIDS / STD / TB] AND
COORDINATION OF [HIV / AIDS / STD / TB] CARE**

(AOD TREATMENT PROGRAM & HEALTH DEPARTMENT STAFF)

[Name of relevant Health Department [HIV / AIDS / STD / TB] unit and staff] (“the Health Department [HIV / AIDS / STD / TB] Unit”) and the [name of alcohol or drug treatment program] (“the Program”) hereby enter into a qualified service organization agreement, whereby the Health Department [HIV / AIDS / STD / TB] Unit agrees to [provide, coordinate and/or monitor] the treatment and / or related services for [HIV / AIDS / STD / TB] being provided to patients of the Program who are diagnosed and reported as having [HIV / AIDS / STD / TB] and are provided [HIV / AIDS / STD / TB]-related services by the Health Department [HIV / AIDS / STD / TB] Unit.

Furthermore, the Health Department [HIV / AIDS / STD / TB] Unit:

(1) acknowledges that in receiving, storing, processing or otherwise dealing with any information from the Program about the patients in the Program, it is fully bound by the provisions of the federal regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2; and

(2) undertakes to resist in judicial proceedings any effort to obtain access to information pertaining to patients otherwise than as expressly provided for in the Federal confidentiality regulations, 42 C.F.R. Part 2.

Executed this _____ day of _____, 200__.

Director
[Name of Health Department
HIV / AIDS / STD / TB Unit
[address]

AOD Program Director
[Name of Program]
[address]

Source:

This sample form is set forth in CSAT/SAMHSA’s TAP 13, Page 22.

HIPAA SAMPLE FORMS

The forms in this subsection only take into account the Federal Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule within 45 C.F.R. Parts 160 & 164.

***REQUIRED DISCLAIMER:** To date, the sample form below is pending review and is NOT “Government approved”. Authorization has been given to distribute this draft form, as long as notice is provided to the recipient of the form that government review and approval status is currently pending. This sample form is created as a general aid for reference use only and does not constitute the rendering of legal or other professional advice by the Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, or its contractor, Social and Health Services, Ltd., a division of ORC Macro, Inc.*

NOTICE OF PRIVACY PRACTICES

Effective Date: _____
[Note that the effective date may not be earlier than the date on which the notice is printed or otherwise published!]

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.

Health information which we receive and/or create about you, personally, in this office, relating to your past, present, or future health, treatment, or payment for health care services, is “protected health information” under the Federal law known as the Health Insurance Portability and Accountability Act (HIPAA). Your health information is further protected by any pertinent state law that is more protective or stringent than HIPAA. This Notice describes how we protect personal health information (otherwise referred to as “protected health information”) we have about you, and how we may use and disclose this information. This Notice also describes your rights with respect to protected health information and how you can exercise those rights.

Uses and disclosures that may be made of your health information:

- **Treatment:** Protected health information received or created by your health care providers in this office will be recorded in your medical record and used in the course of treating you. The sharing of your protected health information may progress to other health care providers outside of this office who are involved in your care, such as referring providers, specialty or consulting physicians, lab technicians, or other providers involved in the provision, coordination, or management of your health care.

• **Payment:** Your protected health information will be used and disclosed in order to obtain payment for treatment and services you receive. A bill may be sent to you, an insurance company, or a third-party payer with accompanying documentation that identifies you, your diagnosis, procedures performed and supplies used, and any other information that may be reasonably required for payment purposes. Your protected health information may also be used or disclosed in other payment related activities, such as claims management activities. We may tell your insurance company about a test or treatment you are going to receive in order to receive prior approval or to determine whether your insurance plan will cover the test or treatment.

• **Health Care Operations:** Your protected health information will be used for the purpose health care operations. Healthcare operations include quality assessment and improvement activities, reviewing the competence or qualifications of healthcare professionals, evaluating practitioner and provider performance, conducting training programs, accreditation, certification, licensing or credentialing activities, as well as business planning, development and management activities, customer services and business restructuring, acquisition, consolidation or merger. These uses and disclosures are necessary to run this office and make sure that all of our patients receive quality care. For example, the medical staff in this office may use your health information to assess the care you received and the outcome of your case compared to others like it. Your information may be reviewed for risk management or quality improvement purposes in our efforts to continually improve the quality and effectiveness of the care and services we provide.

• **Appointment Reminders:** This office reserves the right to contact you, as permitted by law, with appointment reminders or information about treatment alternatives and other health related benefits that may be appropriate to you.

• **Business Associates:** Some or all of your protected health information may be subject to disclosure through contracts for services with business associates outside of this office to assist this office in providing health care. Examples of business associates include billing companies, data processing companies, or companies that provide administrative or specialty services. To protect your health information, we require these Business Associates to follow the same standards held by this office through terms detailed in a written agreement.

• **Facility Directory [typically applicable only to inpatient setting]:** Unless you object, this facility will use your name, room number, general condition, and religious affiliation for directory purposes. This information will be made available to clergy, and, with the exception of religious affiliation, this information will also be disclosed to others who ask for you by name.

• **Individuals Involved in Your Care or Payment of Your Care:** Unless you object or we infer from the circumstances based on our professional judgment that you would likely not object, we may provide protected health information about your condition and/or recovery to a family member, close personal friend, or any other person identified by you who is involved in your medical care. We may also give information to someone who helps pay for your care. Your protected health information may be used or disclosed to notify or assist in notifying

family members, personal representatives, or other persons responsible for your care about your well being or your whereabouts. We may also disclose protected health information to public or private agencies authorized by law to engage in disaster relief efforts to carry out their responsibilities in specific disaster situations.

• **To Avert a Serious Threat to Health or Safety:** This office may disclose protected health information about you if and when such disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public. Any disclosure, however, would only be made to someone who is reasonably able to help prevent the threat.

• **For Health Oversight Activities:** This office may disclose protected health information to health oversight agencies for oversight activities authorized by law, such as audits, civil, administrative or criminal investigations or proceedings, inspections, and licensure or disciplinary actions. For example, we may disclose protected health information to any governmental agency or regulator with whom you may file a complaint or as part of the regulatory agency's investigation or audit.

• **For Judicial & Administrative Proceedings:** If you or your estate is involved in a claim or lawsuit, this office may disclose protected health information about you in response to a court or administrative order. We may also disclose protected health information about you in response to a subpoena, discovery request, or other lawful process by someone else involved in the dispute, so long as it is demonstrated that efforts have been made to tell you about the request or to obtain an order protecting the protected health information requested.

• **For Law Enforcement Purposes:** This office may disclose protected health information in response to a request by a law enforcement official made through a court order, subpoena, warrant, summons or similar process. We may also disclose limited protected health information about you as otherwise permitted by law in crime related circumstances, such as in identifying or locating a suspect, fugitive, material witness or missing person, or when necessary to report a crime in a medical emergency or about criminal conduct in our office.

• **For Public Health Activities:** This office may disclose protected health information about you to public health authorities that are authorized by law to collect information for the purpose of:

- Maintaining vital records, such as births and deaths;
- Reporting child abuse or neglect;
- Preventing or controlling disease, injury, or disability;
- Notifying a person regarding potential exposure to a communicable disease;
- Notifying a person regarding the potential risk for spreading or contracting a disease or condition;
- Reporting reactions to drugs or problems with products or devices; or,
- Notifying individuals if a product or device they may be using has been recalled.

- **As Required by Law:** This office will disclose protected health information required and/or otherwise authorized by Federal, state or local law. This includes, for example, disclosure to comply with reporting requirements by certain professionals of suspected abuse and neglect.
- **Concerning Victims of Abuse, Neglect, or Domestic Violence:** This office may notify the appropriate government authority if we believe a patient has been the victim of abuse, neglect, or domestic violence. We will only make this disclosure if you agree, or when required or authorized by law.
- **Research [typically applicable only to inpatient settings]:** Under certain circumstances, this office may use and disclose your protected health information for research purposes. For example, a research project may involve comparing the health and recovery of all patients who received one test or treatment to those who received another, for the same condition. All research projects, however, must be approved by an Institutional Review Board, or other privacy review board as permitted within the regulations, that has reviewed the research proposal and established protocols to ensure the privacy of your protected health information. In certain instances, we may also disclose your protected health information to researchers preparing to conduct a research project, for example, to help them look for patients with specific medical needs, so long as the medical information they review does not leave our offices and they provide certain assurances.
- **Funeral Directors and Coroners or Medical Examiners:** Your health information may be disclosed consistent with laws governing mortician services. We may release your protected health information to a coroner or medical examiner to assist in identifying a deceased individual or to determine cause of death.
- **Worker's Compensation:** This office will release information to the extent authorized by law in matters of worker's compensation.
- **Organ Procurement Organizations:** If you are an organ donor, this office may release your protected health information to organizations that handle organ procurement or organ, eye or tissue transplantation or to an organ donation bank, as necessary to facilitate organ or tissue donation and transplantation.
- **For Specialized Government Functions:** This office may disclose protected health information about you to Federal officials for the conduct of lawful intelligence, counterintelligence, and other national security activities authorized by law.
- **Correctional Facilities:** This office will release medical information on incarcerated individuals to correctional agents or institutions for the necessary welfare of the individual or for the health and safety of other individuals. The rights outlined in this Notice of Privacy Practices will not be extended to incarcerated individuals.

• **Fundraising Efforts:** This office reserves the right to contact you as part of our fundraising efforts.

• **Other Uses and Disclosure of Protected Health Information:** Other uses and disclosures of protected health information not covered by this Notice will be made only with your written authorization or that of your legal representative. If you or your legal representative authorize us to use or disclose protected health information about you, you or your legal representative may revoke that authorization, in writing, at any time, except to the extent that we have already taken action relying on the authorization. To revoke a prior authorization, you must submit your revocation in writing to directly to this office.

[Revise any of the above HIPAA protections to conform to more stringent protections provided by State law, if any.]

Your rights regarding protected health information we maintain about you:

• **Right to Inspect and Copy:** In most cases, you have the right to inspect and obtain a copy of the protected health information that we maintain about you. To inspect and copy your protected health information, you must submit your request in writing to this office. In order to receive a copy of your protected health information, you may be charged a fee for the photocopying, mailing, or other costs associated with your request. In some very limited circumstances we may, as authorized by law, deny your request to inspect and obtain a copy of your protected health information. You will be notified of a denial to any part or parts of your request. Some denials, by law, are reviewable, and you will be notified regarding the procedures for invoking a right to have a denial reviewed. Other denials, however, as set forth in the law, are not reviewable. Each request will be reviewed individually, and a response will be provided to you in accordance with the law.

• **Right to Amend Your Protected Health Information:** If you believe that your protected health information is incorrect or that an important part of it is missing, you have the right to ask us to amend your protected health information while it is kept by or for us. You must provide your request and your reason for the request in writing, and submit it to this office. We may deny your request if it is not in writing or does not include a reason that supports the request. In addition, we may deny your request if you ask us to amend protected health information that we believe:

- Is accurate and complete;
- Was not created by us, unless the person or entity that created the protected health information is no longer available to make the amendment;
- Is not part of the protected health information kept by or for us; or
- Is not part of the protected health information which you would be permitted to inspect and copy.

If your right to amend is denied, we will notify you of the denial and provide you with instructions on how you may exercise your right to submit a written statement disagreeing with the denial and/or how you may request that your request to amend and a copy of the denial be kept together with the protected health information at issue, and disclosed together with any further disclosures of the protected health information at issue.

• **Right to an Accounting of Disclosures:** You have the right to request an accounting or list of the disclosures that we have made of protected health information about you. This list will not include certain disclosures as set forth in the HIPAA regulations, including those made for treatment, payment, or health care operations, or for purposes of national security, or made pursuant to your authorization or made directly to you. To request this list, you must submit your request in writing to this office. Your request must state the time period from which you want to receive a list of disclosures. The time period may not be longer than six years, and may not include dates before April 14, 2003. Your request should indicate in what form you want the list (for example, on paper or electronically). The first list you request within a 12-month period will be free. We may charge you for responding to any additional requests. We will notify you of the cost involved and you may choose to withdraw or modify your request at that time before any costs are incurred.

• **Right to Request Restrictions:** You have the right to request a restriction or limitation on protected health information we use or disclose about you for treatment, payment or health care operations, or that we disclose to someone who may be involved in your care or payment for your care, like a family member or friend, or for notification purposes as described in this Notice. While we will consider your request, **we are not required to agree to it.** If we do agree to it, we will comply with your request, except in emergency situations where your protected health information is needed to provide you with emergency treatment. We will not agree to restrictions on uses or disclosures that are legally required, or those which are legally permitted and which we reasonably believe to be in the best interest of your health.

• **Right to Request Confidential Communications:** You have the right to request that we communicate with you about protected health information in a certain manner or at a certain location. For example, you can ask that we only contact you at work or by mail. To request confidential communications, you must make your request in writing to this office and specify how or where you wish to be contacted. We will accommodate all reasonable requests.

• **Right to File a Complaint:** If you believe your privacy rights have been violated, you may file a complaint with this office or with the Secretary of the Department of Health and Human Services. To file a complaint with this office, please contact _____ [name, address, phone of your Privacy Officer, or other relevant instructions]. You will not be penalized or otherwise retaliated against for filing a complaint. If you have questions as to how to file a complaint please contact us at _____ [office name and address].

[Revise the above HIPAA patient rights to conform to more generous or stringent rights provided by State law, if any.]

Our responsibilities:

This office is required to:

- Maintain the privacy of your protected health information;
- Provide you with this notice of our legal duties and privacy practices with respect to your protected health information; and,
- Abide by the terms of this Notice while it is in effect.

This office reserves the right to change the terms of this Notice at any time and to make a new Notice with provisions effective for all protected health information that we maintain. In the event that changes are made, this office will notify you of a revised Notice by mail [or state other means of intended notification] at the current address provided on your medical file. [If applicable, this office will post changes on our web site.]

To receive additional information:

For further explanation of this Notice you may contact _____ at _____ . [Fill in blanks with Privacy Official’s name/title and telephone number and any other relevant contact information.]

Availability of Notice of Privacy Practices:

This notice will be posted where registration occurs [or whatever prominent location your office decides to post the notice]. You have a right to receive a copy of this notice, and all individuals receiving care will be given a hard copy. [If applicable to your practice you may include: “*This notice will be maintained and available for downloading at the following Web site address: _____.*”]

Acknowledgement:

I hereby acknowledge that I received a copy of this Notice of Privacy Practices.

Patient Signature

Date

Source: This sample form was drafted by Social and Health Services, Ltd., a division of ORC Macro.

CHECKLIST TO ENSURE YOUR PRIVACY NOTICE COMPLIES WITH HIPAA REGULATIONS

HIPAA Privacy Regulation Text

§ 164.520 Notice of privacy practices for protected health information.

(a) *Standard: notice of privacy practices.*

(1) *Right to notice.* Except as provided by paragraph (a)(2) or (3) of this section, an individual as right to adequate notice of the uses and disclosures of protected health information that may be made by the covered entity, 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; or

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

(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 that is a covered entity.

(b) *Implementation specifications: content of notice.*

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

(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 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.

(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.* 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 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 health-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

(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 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;

(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.

(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).

(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, 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).

(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 and distribute 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.

(c) *Implementation specifications: provision of notice.* A covered entity must make the notice required by this section available on request to any person 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.

(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.

(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.

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

(i) Provide the notice:

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

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

(ii) Except in an emergency treatment situation, make a good faith effort to obtain a written acknowledgment of receipt of the notice provided in accordance with paragraph (c)(2)(i) of this section, and if not obtained, document its good faith efforts to obtain such acknowledgment and the reason why the acknowledgment was not obtained;

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

(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.* Covered entities that participate in organized health care arrangements 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 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.

***REQUIRED DISCLAIMER:** To date, the sample form below is pending review and is NOT "Government approved". Authorization has been given to distribute this draft form, as long as notice is provided to the recipient of the form that government review and approval status is currently pending. This sample form is created as a general aid for reference use only and does not constitute the rendering of legal or other professional advice by the Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, or its contractor, Social and Health Services, Ltd., a division of ORC Macro, Inc.*

**AUTHORIZATION FOR THE RELEASE OF
PROTECTED HEALTH INFORMATION**

I, _____, authorize
(Name of patient)

(Name or general designation of program making disclosure)

to disclose to _____ the
(Name of person or organization to which disclosure is to be made)

following information: _____
(Specific nature of the information, as limited as possible)

The purpose of the disclosure authorized herein is to: _____
(Specific purpose of disclosure)

I understand that my records are currently protected under the Federal privacy regulations within the Health Insurance Portability and Accountability Act (HIPAA), 45 C.F.R. Parts 160 & 164. I further understand that the information specified above will be disclosed pursuant to this authorization, and that the recipient of the information may re-disclose the information and it may no longer be protected by the HIPAA privacy law.

I understand that I may revoke this authorization in writing at any time except to the extent that action has been taken in reliance on it, and that in any event this authorization expires automatically as follows:

(Specification of the date, event, or condition upon which this consent expires)

Should I decide to revoke this authorization prior to its expiration, I understand that I must do so in writing as follows:

(State the procedure for submitting written revocation [i.e., the position title and address of the person to whom the revocation needs to be delivered].)

I understand that the covered entity seeking this authorization may not conditioning treatment, payment, enrollment in the health plan, or eligibility for benefits on whether I sign the authorization.

*[OR, where conditioning is appropriate, substitute the above paragraph, such as:
I understand that the covered entity seeking this authorization is permitted under the HIPAA regulations, in accordance with 45 C.F.R. Section 164.508(b)(4), to condition my signing of this authorization on the provision of treatment, payment, enrollment in the health plan or eligibility for benefits, and that by refusing to sign this authorization, I may be faced with the following consequences:*

(State consequences)]

*[If the authorization is for marketing purposes and the covered entity may obtain remuneration, then add a paragraph to the authorization, such as:
This authorization is for the use and/or disclosure of protected health information for marketing purposes, and the covered entity seeking this authorization will obtain direct or indirect remuneration from a third party in this regard.]*

DRAFT: FOR EXAMPLE PURPOSES ONLY

I understand that I am entitled to receive a copy of this authorization after it is signed.

Dated: _____

Signature of patient

Signature of parent, guardian, or authorized
representative, when required

*Source: This sample HIPAA authorization was drafted by Social and Health Services, Ltd., a
division of ORC Macro.*



SAMPLE BUSINESS ASSOCIATE CONTRACT PROVISIONS

(Published in FR 67 No.157 pg.53182, 53264 (August 14, 2002))

Statement of Intent

The Department provides these sample business associate contract provisions in response to numerous requests for guidance. This is only sample language. These provisions are designed to help covered entities more easily comply with the business associate contract requirements of the Privacy Rule. However, use of these sample provisions is not required for compliance with the Privacy Rule. The language may be amended to more accurately reflect business arrangements between the covered entity and the business associate.

These or similar provisions may be incorporated into an agreement for the provision of services between the entities or they may be incorporated into a separate business associate agreement. These provisions only address concepts and requirements set forth in the Privacy Rule and alone are not sufficient to result in a binding contract under State law. They do not include many formalities and substantive provisions that are required or typically included in a valid contract. Reliance on this sample is not sufficient for compliance with State law and does not replace consultation with a lawyer or negotiations between the parties to the contract.

Furthermore, a covered entity may want to include other provisions that are related to the Privacy Rule but that are not required by the Privacy Rule. For example, a covered entity may want to add provisions in a business associate contract in order for the covered entity to be able to rely on the business associate to help the covered entity meet its obligations under the Privacy Rule. In addition, there may be permissible uses or disclosures by a business associate that are not specifically addressed in these sample provisions, for example having a business associate create a limited data set. These and other types of issues will need to be worked out between the parties.

Sample Business Associate Contract Provisions¹

Definitions (alternative approaches)

Catch-all definition:

Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in the Privacy Rule.

Examples of specific definitions:

- a. Business Associate. "Business Associate" shall mean [Insert Name of Business Associate].
- b. Covered Entity. "Covered Entity" shall mean [Insert Name of Covered Entity].
- c. Individual. "Individual" shall have the same meaning as the term "individual" in 45 C.F.R. § 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 C.F.R. § 164.502(g).
- d. Privacy Rule. "Privacy Rule" shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 C.F.R. Part 160 and Part 164, Subparts A and E.
- e. Protected Health Information. "Protected Health Information" shall have the same meaning as the term "protected health information" in 45 C.F.R. § 164.501, limited to the information created or received by Business Associate from or on behalf of Covered Entity.
- f. Required By Law. "Required By Law" shall have the same meaning as the term "required by law" in 45 C.F.R. § 164.501.
- g. Secretary. "Secretary" shall mean the Secretary of the Department of Health and Human Services or his designee.

Obligations and Activities of Business Associate

- a. Business Associate agrees to not use or disclose Protected Health Information other than as permitted or required by the Agreement or as Required By Law.
- b. Business Associate agrees to use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this Agreement.
- c. Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of Protected Health Information by Business Associate in violation of the requirements of this Agreement. [This provision may be included if it is appropriate for the Covered Entity to pass on its duty to mitigate damages to a Business Associate.]
- d. Business Associate agrees to report to Covered Entity any use or disclosure of the Protected Health Information not provided for by this Agreement of which it becomes aware.
- e. Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by Business Associate on behalf of Covered Entity agrees to the same restrictions and conditions that apply through this Agreement to Business Associate with respect to such information.
- f. Business Associate agrees to provide access, at the request of Covered Entity, and in the time and manner [Insert negotiated terms], to Protected Health Information in a Designated Record Set, to Covered Entity or, as directed by Covered Entity, to an Individual in order to meet the requirements under 45 C.F.R. § 164.524. [Not necessary if business associate does not have protected health information in a designated record set.]
- g. Business Associate agrees to make any amendment(s) to Protected Health Information in a Designated Record Set that the Covered Entity directs or agrees to pursuant to 45 C.F.R. § 164.526 at the request of Covered Entity or an Individual, and in the time and manner [Insert negotiated terms]. [Not necessary if business associate does not have protected health information in a designated record set.]

- h. Business Associate agrees to make internal practices, books, and records, including policies and procedures and Protected Health Information, relating to the use and disclosure of Protected Health Information received from, or created or received by Business Associate on behalf of, Covered Entity available [to the Covered Entity, or] to the Secretary, in a time and manner [Insert negotiated terms] or designated by the Secretary, for purposes of the Secretary determining Covered Entity's compliance with the Privacy Rule.
- i. Business Associate agrees to document such disclosures of Protected Health Information and information related to such disclosures as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 C.F.R. § 164.528.
- j. Business Associate agrees to provide to Covered Entity or an Individual, in time and manner [Insert negotiated terms], information collected in accordance with Section [Insert Section Number in Contract Where Provision (i) Appears] of this Agreement, to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 C.F.R. § 164.528.

Permitted Uses and Disclosures by Business Associate

General Use and Disclosure Provisions [(a) and (b) are alternative approaches]

a. Specify purposes:

Except as otherwise limited in this Agreement, Business Associate may use or disclose Protected Health Information on behalf of, or to provide services to, Covered Entity for the following purposes, if such use or disclosure of Protected Health Information would not violate the Privacy Rule if done by Covered Entity or the minimum necessary policies and procedures of the Covered Entity:
[List Purposes].

b. Refer to underlying services agreement:

Except as otherwise limited in this Agreement, Business Associate may use or disclose Protected Health Information to perform functions, activities, or services for, or on behalf of, Covered Entity as specified in [Insert Name of Services Agreement], provided that such use or disclosure would not violate the Privacy Rule if done by Covered Entity or the minimum necessary policies and procedures of the Covered Entity.

Specific Use and Disclosure Provisions [only necessary if parties wish to allow Business Associate to engage in such activities]

- a. Except as otherwise limited in this Agreement, Business Associate may use Protected Health Information for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate.
- b. Except as otherwise limited in this Agreement, Business Associate may disclose Protected Health Information for the proper management and administration of the

Business Associate, provided that disclosures are Required By Law, or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as Required By Law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.

- c. Except as otherwise limited in this Agreement, Business Associate may use Protected Health Information to provide Data Aggregation services to Covered Entity as permitted by 42 C.F.R. § 164.504(e)(2)(i)(B).
- d. Business Associate may use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with § 164.502(j)(1).

Obligations of Covered Entity

Provisions for Covered Entity to Inform Business Associate of Privacy Practices and Restrictions [provisions dependent on business arrangement]

- a. Covered Entity shall notify Business Associate of any limitation(s) in its notice of privacy practices of Covered Entity in accordance with 45 C.F.R. § 164.520, to the extent that such limitation may affect Business Associate's use or disclosure of Protected Health Information.
- b. Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, to the extent that such changes may affect Business Associate's use or disclosure of Protected Health Information.
- c. Covered Entity shall notify Business Associate of any restriction to the use or disclosure of Protected Health Information that Covered Entity has agreed to in accordance with 45 C.F.R. § 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of Protected Health Information.

Permissible Requests by Covered Entity

Covered Entity shall not request Business Associate to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule if done by Covered Entity. [Include an exception if the Business Associate will use or disclose protected health information for, and the contract includes provisions for, data aggregation or management and administrative activities of Business Associate].

Term and Termination

- a. Term. The Term of this Agreement shall be effective as of [Insert Effective Date], and shall terminate when all of the Protected Health Information provided by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity, or, if it is infeasible to return or destroy Protected Health Information, protections are extended to such information, in accordance with the termination provisions in this Section. [Term may differ.]

- b. Termination for Cause. Upon Covered Entity's knowledge of a material breach by Business Associate, Covered Entity shall either:
1. Provide an opportunity for Business Associate to cure the breach or end the violation and terminate this Agreement [and the _____ Agreement/ sections ____ of the _____ Agreement] if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity;
 2. Immediately terminate this Agreement [and the _____ Agreement/ sections ____ of the _____ Agreement] if Business Associate has breached a material term of this Agreement and cure is not possible; or
 3. If neither termination nor cure are feasible, Covered Entity shall report the violation to the Secretary.

[Bracketed language in this provision may be necessary if there is an underlying services agreement. Also, opportunity to cure is permitted, but not required by the Privacy Rule.]

- c. Effect of Termination.
1. Except as provided in paragraph (2) of this section, upon termination of this Agreement, for any reason, Business Associate shall return or destroy all Protected Health Information received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the Protected Health Information.
 2. In the event that Business Associate determines that returning or destroying the Protected Health Information is infeasible, Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction infeasible. Upon [Insert negotiated terms] that return or destruction of Protected Health Information is infeasible, Business Associate shall extend the protections of this Agreement to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such Protected Health Information.

Miscellaneous

- a. Regulatory References. A reference in this Agreement to a section in the Privacy Rule means the section as in effect or as amended.
- b. Amendment. The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the Privacy Rule and the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191.
- c. Survival. The respective rights and obligations of Business Associate under Section [Insert Section Number Related to "Effect of Termination"] of this Agreement shall survive the termination of this Agreement.

- d. Interpretation. Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the Privacy Rule.

¹ *Words or phrases contained in brackets are intended as either optional language or as instructions to the users of these sample provisions and are not intended to be included in the contractual provisions.*

Last revised: August 14, 2002

Source:

These sample Business Associate Contract Provisions were pulled from the Office for Civil Rights' HIPAA Web site at <http://www.hhs.gov/ocr/hipaa/contractprov.html>.

***REQUIRED DISCLAIMER:** To date, the sample form below is pending review and is NOT “Government approved”. Authorization has been given to distribute this draft form, as long as notice is provided to the recipient of the form that government review and approval status is currently pending. This sample form is created as a general aid for reference use only and does not constitute the rendering of legal or other professional advice by the Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, or its contractor, Social and Health Services, Ltd., a division of ORC Macro, Inc.*

BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement (“BA Agreement”) is entered into on this _____ day of _____, 20____, by and between _____ and _____.

(Covered Entity) (Business Associate)

Recitals

- A. Covered Entity will make available and/or provide certain Protected Health Information (as defined below) to Business Associate in the course of the parties’ relationship.
- B. In order to protect the privacy of the Protected Health Information and to comply with HIPAA and the HIPAA Regulations (as defined below), Covered Entity and Business Associate desire to enter into this BA Agreement setting forth the terms and conditions of use and disclosure of Protected Health Information.

In consideration of the mutual promises set forth below, the parties agree as follows:

Article 1: Definitions

- 1.1 **Business Associate.** “Business Associate” shall mean [Insert name of Business Associate].
- 1.2 **Covered Entity.** “Covered Entity” shall mean [Insert name of Covered Entity].

- 1.3 **Individual.** “Individual” shall have the same meaning as the term "individual" in 45 CFR § 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 CFR § 164.502(g).
- 1.4 **HIPAA.** “HIPAA” means the Health Insurance Portability & Accountability Act of 1996, P.L. 104-91.
- 1.5 **HIPAA Regulations.** “HIPAA Regulations” mean the regulations promulgated under HIPAA by the U.S. Department of Health and Human Services, including the Privacy Rule.
- 1.6 **Privacy Rule.** “Privacy Rule” shall mean the Standards for Privacy of Individually Identifiable Health Information in 45 CFR Part 160 and Part 164, Subparts A and E.
- 1.7 **Protected Health Information.** “Protected Health Information” shall have the same meaning as the term “protected health information” in 45 CFR § 164.501, limited to the information created or received by Business Associate from or on behalf of the Covered Entity.
- 1.8 **Required By Law.** “Required By Law” shall have the same meaning as the term "required by law" in 45 CFR § 164.501.
- 1.9 **Secretary.** “Secretary” shall mean the Secretary of the Department of Health and Human Services or the Secretary’s designee.
- 1.10 **General Rule.** Capitalized terms not otherwise defined in this BA Agreement shall have the same meaning as those terms in the Privacy Rule.

Article 2: Obligations and Activities of Business Associate

- 2.1 **Prohibitions.** Business Associate agrees to not use or disclose Protected Health Information other than as permitted or required by the BA Agreement or as Required By Law.
- 2.2 **Safeguards.** Business Associate agrees to implement and use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this BA Agreement.
- 2.3 **Mitigation.** Business Associate agrees to mitigate promptly, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of Protected

Health Information by Business Associate in violation of the BA Agreement, the Privacy Rule, or other applicable federal or state law.

- 2.4 **Reports of Improper Use or Disclosure.** Business Associate agrees to immediately report to Covered Entity any use or disclosure of the Protected Health Information not provided for by this BA Agreement of which it becomes aware. Business Associate also agrees to immediately report to Covered Entity about any complaint that the Business Associate receives concerning the handling of Protected Health Information or compliance with this BA Agreement.
- 2.5 **Disclosures to Agents and Subcontractors.** Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by Business Associate on behalf of Covered Entity agrees to the same restrictions and conditions that apply through this Agreement to Business Associate with respect to such information.
- 2.6 **Access.** To enable the Covered Entity to fulfill its obligations under the Privacy Rule, Business Associate agrees to make Protected Health Information in Designated Record Sets that are maintained by Business Associates or its agents or subcontractors available to Covered Entity for inspection and copying within ten (10) days of a request by Covered Entity. If an Individual requests inspection and copying of Protected Health Information directly from Business Associate or its agents or subcontractors, Business Associate shall notify the Covered Entity in writing within five (5) business days of receipt of the request, and shall defer to, and comply with, Covered Entity's direction in a timely manner regarding the response to the Individual regarding the request for inspection and copying.

[This is an example. The specific terms outlined in this paragraph should accurately reflect the agreed upon terms following discussions and negotiations between the parties.]

- 2.7 **Amendment.** To enable the Covered Entity to fulfill its obligations under the Privacy Rule, Business Associate agrees to make any amendment(s) to Protected Health Information in a Designated Record Set that are maintained by Business Associate or its agents or subcontractors that the Covered Entity directs or agrees to pursuant to 45 CFR § 164 within ten (10) days of a request by Covered Entity. If an Individual requests amendment of Protected Health Information directly from Business Associate or its agents or subcontractors, Business Associate shall notify the Covered Entity in writing within five (5) business days of receipt of the request, and shall defer to, and comply with, Covered Entity's direction in a timely manner regarding the response to the Individual regarding the request for amendment.

[This is an example. The specific terms outlined in this paragraph should accurately reflect the agreed upon terms following discussions and negotiations between the parties.]

2.8 **Federal Government Officials.** Business Associate agrees to make internal practices, books, and records, including policies and procedures and Protected Health Information, relating to the use and disclosure of Protected Health Information received from, or created or received by Business Associate on behalf of, Covered Entity available to the Secretary as designated by the Secretary, for purposes of the Secretary determining Covered Entity's compliance with the Privacy Rule. Business Associate shall notify Covered Entity regarding any Protected Health Information that Business Associate provides to the Secretary concurrently with providing such Protected Health Information to the Secretary, and upon Covered Entity's request, shall provide Covered Entity with a duplicate copy of such Protected Health Information.

[This is an example. The specific terms outlined in this paragraph should accurately reflect the agreed upon terms following discussions and negotiations between the parties.]

2.9 **Documentation of Disclosures.** Business Associate agrees to implement a process for documenting such disclosures of Protected Health Information and information related to such disclosures as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR § 164.528.

2.10 **Accounting of Disclosures.** Business Associate agrees to provide to Covered Entity the information collected in accordance with Section 2.9 of this BA Agreement within ten (10) days of the Covered Entity's request in order to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR § 164.528. If an individual requests an accounting directly from Business Associate or its agents or subcontractors, Business Associate must notify Covered Entity in writing within five (5) business days of the request, and shall defer to, and comply in a timely manner with, Covered Entity's direction regarding the response to the Individual regarding the request for an accounting.

[This is an example. The specific terms outlined in this paragraph should accurately reflect the agreed upon terms following discussions and negotiations between the parties.]

Article 3: Permitted Uses and Disclosures by Business Associate

3.1 **Specific Purposes.** Except as otherwise limited in this BA Agreement, Business Associate may use or disclose Protected Health Information on behalf of, or to provide services to, Covered Entity for the following purposes, provided that such use or disclosure of Protected Health Information would not violate the Privacy Rule if done by Covered Entity or the minimum necessary policies and procedures of the Covered Entity:

- 3.5 **Reporting Law Violations.** Business Associate may use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with § 164.502(j)(1).

[This is an optional provision, if the parties wish to allow the Business Associate to engage in this activity. Otherwise, it may be deleted.]

Article 4: Obligations of Covered Entity

- 4.1 **Notice of Privacy Practices.** Covered Entity shall notify Business Associate of any limitation(s) in its notice of privacy practices of Covered Entity in accordance with 45 CFR § 164.520, to the extent that such limitation may affect Business Associate's use or disclosure of Protected Health Information.
- 4.2 **Individual Permission.** Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, to the extent that such changes may affect Business Associate's use or disclosure of Protected Health Information.
- 4.3 **Restrictions.** Covered Entity shall notify Business Associate of any restriction to the use or disclosure of Protected Health Information that Covered Entity has agreed to in accordance with 45 CFR § 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of Protected Health Information.
- 4.4 **Prohibited Requests.** Covered Entity shall not request Business Associate to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule if done by Covered Entity. This provision does not otherwise affect the Business Associate's permitted use and disclosure of Protected Health Information for data aggregation (permitted in 3.4 above) and/or management and administrative activities (permitted in 3.3 above).

Article 5: Term and Termination

- 5.1 **Term.** The Term of this BA Agreement shall be effective as of _____, and shall terminate when all of the Protected
[Insert Effective Date]

Health Information provided by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity, or, if it is infeasible to return or destroy Protected Health Information, protections are extended to such information, in accordance with the termination provisions in this Section.

[Note: Term may differ, and should accurately reflect the agreed upon term following discussions and negotiations between the parties.]

5.2 **Termination for Cause.** Upon Covered Entity's knowledge of a material breach by Business Associate, Covered Entity shall either:

- A. Provide an opportunity for Business Associate to cure the breach or end the violation, and terminate this Agreement if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity;
- B. Immediately terminate this Agreement if Business Associate has breached a material term of this Agreement and cure is not possible; or
- C. If neither termination nor cure is feasible, Covered Entity shall report the violation to the Secretary.

[Note that the opportunity to cure is permitted, but not required by the Privacy Rule. The above paragraphs can be replaced with: "A. Immediately terminate this Agreement if Business Associate has breached a material term of this Agreement", and "B. If neither termination are feasible, Covered Entity shall report the violation to the Secretary."]

5.3 **Effect of Termination.**

- A. Except as provided in paragraph (B) of this section, upon termination of this Agreement, for any reason, Business Associate shall return or destroy all Protected Health Information received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the Protected Health Information.
- B. In the event that Business Associate determines that returning or destroying the Protected Health Information is infeasible, Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction infeasible. Business Associate shall thereafter extend the protections of this Agreement to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the

return or destruction infeasible, for so long as Business Associate maintains such Protected Health Information.

- 5.4 **Survival.** The respective rights and obligations of Business Associate under this Article 5 shall survive the termination of this BA Agreement.

Article 6: Miscellaneous

- 6.1 **Regulatory References.** A reference in this Agreement to a section in the Privacy Rule means the section as in effect or as amended.
- 6.2 **Amendment.** The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the Privacy Rule and the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191.
- 6.3 **Interpretation.** Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the Privacy Rule.
- 6.4 **State Law.** In addition to HIPAA and the HIPAA Regulations, Business Associate shall comply with all applicable state and federal privacy and security laws.
- 6.5 **Notices.** Under the terms of this BA Agreement, either party shall be deemed as being given notice, if delivered personally, or if mailed by first class United States mail, postage prepaid, and addressed as follows:

If to Covered Entity:

If to Business Associate:

Attention: _____

Attention: _____

[State full addresses and name contact persons.]

[This is an example. The method of notification outlined in this paragraph should accurately reflect the negotiations and agreed upon terms between the parties.]

6.6 **Notification of Change of Address.** If Covered Entity and/or Business Associate change its address for notification purposes, it shall promptly notify the other party to this BA Agreement in writing and clearly state the new address and the effective date for the change of address.

6.7 **Good Faith.** The parties to this BA Agreement agree to exercise good faith in the performance of this contract.

6.8 **Attorneys Fees.** Each party to this BA agreement agrees to bear its own legal expenses and any other cost incurred for actions or proceedings brought about by the enforcement of this contract, or from an alleged dispute, breach, default, misrepresentation, or injunctive action associated with the provisions of this contract.

[Another alternative would be to require the Business Associate to maintain insurance coverage for itself and its agents and subcontractors against any claim or claims for damages that arise under this BA Agreement. And, to require the Business Associate to indemnify, hold harmless, and defend Covered Entity from and against any and all claims, losses, liabilities, costs, and other expenses, including reasonable attorney's fees and costs, incurred as a result of, or arising out of any act or omission of Business Associate, its agents or subcontractors, under this BA Agreement.]

6.9 **Disputes.** Any controversy or claim arising from or relating to the terms defined under this contract are subject to settlement by compulsory arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association, except for injunctive relief which may be sought by the Covered Entity to prevent or stop the unauthorized use or disclosure of information by Business Associate or any agent, contractor, or third party that received information from Business Associate.

[This is one option, but it really depends on negotiations. Compulsory arbitration may not be desired or agreed to by the parties. This paragraph may be left out or altered to conform to the agreed upon terms of the parties following discussions and negotiations.]

6.10 **Entire Agreement.** This BA Agreement sets forth the entire agreement between the Covered Entity and Business Associate. The terms of this contract shall be binding on the parties. Neither party has the authority to reassign this agreement without the other's written consent.

[Note: Any other agreements made between the parties following negotiations that are not otherwise set forth above in this BA Agreement should be inserted so that this agreement clearly reflects the entire agreement of the parties. Also, be sure to include any other or additional provisions required by your respective state law.]

IN WITNESS WHEREOF, the parties hereto have duly executed this BA Agreement as of the date set forth in the first paragraph of this agreement.

BUSINESS ASSOCIATE:

COVERED ENTITY:

Signature

Signature

Print Name

Print Name

Title

Title

Source:

This sample Business Associate Agreement was drafted by Social and Health Services, Ltd., a division of ORC Macro.

[Example of a] DATA USE AGREEMENT

AGREEMENT FOR USE OF CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) DATA CONTAINING INDIVIDUAL-SPECIFIC INFORMATION

In order to secure data that resides in a CMS Privacy Act System of Records, and in order to ensure the integrity, security, and confidentiality of information maintained by the CMS, and to permit appropriate disclosure and use of such data as permitted by law, CMS and _____ enter into this agreement to comply with the following specific paragraphs.

1. This Agreement is by and between the Centers for Medicare & Medicaid Services (CMS), a component of the U.S. Department of Health and Human Services (DHHS), and _____, hereinafter termed "User."
2. This Agreement addresses the conditions under which CMS will disclose and the User will obtain and use the CMS data file(s) specified in section 7. This Agreement supersedes any and all agreements between the parties with respect to the use of data from the files specified in section 7 and preempts and overrides any instructions, directions, agreements, or other understanding in or pertaining to any grant award or other prior communication from the Department of Health and Human Services or any of its components with respect to the data specified herein. Further, the terms of this Agreement can be changed only by a written modification to this Agreement or by the parties adopting a new agreement. The parties agree further that instructions or interpretations issued to the User concerning this Agreement or the data specified herein, shall not be valid unless issued in writing by the CMS point-of-contact specified in section 5 or the CMS signatory to this Agreement shown in item 23.
3. The parties mutually agree that CMS retains all ownership rights to the data file(s) referred to in this Agreement, and that the User does not obtain any right, title, or interest in any of the data furnished by CMS.
4. The parties mutually agree that the following named individual is designated as Custodian of the file(s) on behalf of the User and the person will be responsible for the observance of all conditions of use and for establishment and maintenance of security arrangements as specified in this Agreement to prevent unauthorized use. The User agrees to notify CMS within fifteen (15) days of any change of custodianship. The parties mutually agree that CMS may disapprove the appointment of a custodian or may require the appointment of a new custodian at any time.

(Name of Custodian)

(Company/Organization)

(Street Address)

(City/State/ZIP Code)

(Phone No. - Including Area Code and E-Mail Address, If Applicable)

5. The parties mutually agree that the following named individual will be designated as point-of-contact for the Agreement on behalf of CMS.

(Name of Contact)

(Title/Component)

(Street Address)

(Mail Stop)

(City/State/ZIP Code)

(Phone No. - Including Area Code and E-Mail Address, If Applicable)

6. The User represents, and in furnishing the data file(s) specified in section 7 CMS relies upon such representation, that such data file(s) will be used solely for the following purpose(s).

The User represents further that the facts and statements made in any study or research protocol or project plan submitted to CMS for each purpose are complete and accurate. Further, the User represents that said study protocol(s) or project plans, as have been approved by CMS or other appropriate entity as CMS may determine, represent the total use(s) to which the data file(s) specified in section 7 will be put.

The User represents further that, except as specified in an Attachment to this Agreement or except as CMS shall authorize in writing, the User shall not disclose, release, reveal, show, sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement to any person. The User agrees that, within the User organization, access to the data covered by this Agreement shall be limited to the minimum number of individuals necessary to achieve the purpose stated in this section and to those individuals on a need-to-know basis only.

7. The following CMS data file(s) is/are covered under this Agreement.

File	Year(s)
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

8. The parties mutually agree that the aforesaid file(s) (and/or any derivative file(s) [includes any file that maintains or continues identification of individuals]) may be retained by the User until, hereinafter known as the "retention date." The User agrees to notify CMS within 30 days of the completion of the purpose specified in section 6 if the purpose is completed before the aforementioned retention date. Upon such notice or retention date, whichever occurs sooner, CMS will notify the User either to return all data files to CMS at the User's expense or to destroy such data. If CMS elects to have the User destroy the data, the User agrees to certify the destruction of the files in writing within 30 days of receiving CMS's instruction. A statement certifying this action must be sent to CMS. If CMS elects to have the data returned, the User agrees to return all files to CMS within 30 days of receiving notice to that effect. The User agrees that no data from CMS records, or any parts thereof, shall be retained when the aforementioned file(s) are returned or destroyed unless authorization in writing for the retention of such file(s) has been received from the appropriate Systems Manager or the person designated in item number 23 of this Agreement. The User acknowledges that stringent adherence to the aforementioned retention date is required, and that the User shall ask CMS for instructions under this paragraph if instructions have not been received after 30 days after the retention date.

The Agreement may be terminated by either party at any time for any reason upon 30 days written notice. Upon such notice, CMS will cease releasing data to the User under this Agreement and will notify the User either to return all previously released data files to CMS at the User's expense or destroy such data, using the same procedures stated in the above paragraph of this section. Sections 3, 6, 8, 11, 12, 13, 14, 16, 17 and 18 shall survive

termination of this Agreement.

9. The User agrees to establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use or access to it. The safeguards shall provide a level and scope of security that is not less than the level and scope of security established by the Office of Management and Budget (OMB) in OMB Circular No. A-130, Appendix III--Security of Federal Automated Information Systems (<http://www.whitehouse.gov/omb/circulars/a130/a130.html>), which sets forth guidelines for security plans for automated information systems in Federal agencies. The User acknowledges that the use of unsecured telecommunications, including the Internet, to transmit individually identifiable or deducible information derived from the file(s) specified in section 7 is prohibited. Further, the User agrees that the data must not be physically moved or transmitted in any way from the site indicated in item number 4 without written approval from CMS.

10. The User agrees that the authorized representatives of CMS or DHHS Office of the Inspector General will be granted access to premises where the aforesaid file(s) are kept for the purpose of inspecting security arrangements confirming whether the User is in compliance with the security requirements specified in paragraph 9.

11. The User agrees that no findings, listing, or information derived from the file(s) specified in section 7, with or without identifiers, may be released if such findings, listing, or information contain any combination of data elements that might allow the deduction of a beneficiary's identification without first obtaining written authorization from the appropriate System Manager or the person designated in item number 23 of this Agreement. Examples of such data elements include but are not limited to geographic indicator, age, sex, diagnosis, procedure, admission/discharge date(s), or date of death. The User agrees further that CMS shall be the sole judge as to whether any finding, listing, information, or any combination of data extracted or derived from CMS's files identifies or would, with reasonable effort, permit one to identify an individual or to deduce the identity of an individual to a reasonable degree of certainty.

12. The User agrees that, absent express written authorization from the appropriate System Manager or the person designated in item number 23 of this Agreement to do so, the User shall make no attempt to link records included in the file(s) specified in section 7 to any other identifiable source of information. This includes attempts to link to other CMS data file(s). The inclusion of linkage of specific files in a study protocol approved in accordance with section 6 is considered express written authorization from CMS.

13. The User agrees to submit to CMS a copy of all findings within 30 days of making such findings. The parties mutually agree that the User has made findings with respect to the data covered by this Agreement when the User prepares any report or other writing for submission to any third party (including but not limited to any manuscript to be submitted for publication) concerning any purpose specified in section 6 (regardless of whether the report or other writing expressly refers to such purpose, to CMS, or to the files specified in section 7 or any data derived from such files). The User agrees not to submit such findings to any third party until receiving CMS's approval to do so. CMS agrees to make determination about approval and to notify the user within 4 to 6 weeks after receipt of findings. CMS review of the findings is for the sole

purpose of assuring that data confidentiality is maintained and that individual beneficiaries could not be identified. CMS may withhold approval for publication only if it determines that the format in which data are presented may result in identification of individual beneficiaries. The User agrees further to submit its findings to the National Technical Information Service (NTIS, 5285 Port Royal Road, Springfield, Virginia 22161) within 30 days of receiving notice from CMS to do so.

14. The User understands and agrees that they may not reuse original or derivative data file(s) without prior written approval from the appropriate System Manager or the person designated in section 23 of this Agreement.

15. The parties mutually agree that the following specified Attachments are part of this Agreement:

16. The User agrees that in the event CMS determines or has a reasonable belief that the User has made or may have made disclosure of the aforesaid file(s) that is not authorized by this Agreement or other written authorization from the appropriate System Manager or the person designated in item number 23 of this Agreement, CMS in its sole discretion may require the User to: (a) promptly investigate and report to CMS the User's determinations regarding any alleged or actual unauthorized disclosure, (b) promptly resolve any problems identified by the investigation; (c) if requested by CMS, submit a formal response to an allegation of unauthorized disclosure; (d) if requested by CMS, submit a corrective action plan with steps designed to prevent any future unauthorized disclosures; and (e) if requested by CMS, return data files to CMS. The User understands that as a result of CMS's determination or reasonable belief that unauthorized disclosures have taken place, CMS may refuse to release further CMS data to the User for a period of time to be determined by CMS.

17. The User hereby acknowledges that criminal penalties under §1106(a) of the Social Security Act (42 U.S.C. §1306(a)), including a fine not exceeding \$10,000 or imprisonment not exceeding 5 years, or both, may apply with to disclosures of information that are covered by §1106 and that are not authorized by regulation or by Federal law. The User further acknowledges that criminal penalties under the Privacy Act (5 U.S.C. §552a(i) (3)) may apply if it is determined that the Requestor or Custodian, or any individual employed or affiliated therewith, knowingly and willfully obtained the file(s) under false pretenses. Any person found guilty under the Privacy Act shall be guilty of a misdemeanor and fined not more than \$5,000.

Finally, the User acknowledges that criminal penalties may be imposed under 18 U.S.C. § 641 if it is determined that the User, or any individual employed or affiliated therewith, has taken or converted to his own use data file(s), or received the file(s) knowing that they were stolen or converted. Under such circumstances, they shall be fined under Title 18 or imprisoned not more than ten years, or both; but if the value of such property does not exceed the sum of \$1,000, they shall be fined under Title 18 or imprisoned not more than one year, or both.

18. By signing this Agreement, the User agrees to abide by all provisions set out in this Agreement for protection of the data file(s) specified in section 7, and acknowledges having received notice of potential criminal or administrative penalties for violation of the terms of the Agreement.

19. On behalf of the User the undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to all the terms specified herein.

(Name and Title of Individual - Typed or Printed)

(Company/Organization)

(Street Address)

(City/State/ZIP Code)

(Phone No. - Including Area Code and E-Mail Address, If Applicable)

(Signature)

(Date)

20. The Custodian, as named in paragraph 4, hereby acknowledges his/her appointment as Custodian of the aforesaid file(s) on behalf of the User, and agrees to comply with all of the provisions of this Agreement on behalf of the User.

(Typed or Printed Name and Title of Custodian of File(s))

(Signature)

(Date)

21. The disclosure provision(s) that allows the discretionary release of CMS data for the purpose(s) stated in paragraph 6 follow(s). (To be completed by CMS staff.)

22. On behalf of _____ the undersigned individual hereby acknowledges that the aforesaid Federal agency sponsors or otherwise supports the User's request for and use of CMS data, agrees to support CMS in ensuring that the User maintains and uses CMS's data in accordance with the terms of this Agreement, and agrees further to make no statement to the User concerning the interpretation of the terms of this Agreement and to refer all question of such interpretation or compliance with the terms of this Agreement to the CMS official named in item number 23 (or to his or her successor).

(Typed or Printed Name and Title of Federal Representative)

(Signature)

(Date)

(Phone No. - Including Area Code and E-Mail Address, If Applicable)

23. On behalf of CMS the undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to all the terms specified herein.

(Typed or Printed Name and Title of CMS Representative)

(Signature)

(Date)

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0734. The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, N2-14-26, Baltimore, Maryland 21244-1850 and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

Source:

This Data Use Agreement was pulled as an example from the Centers for Medicare and Medicaid (CMS) HIPAA Web site at <http://cms.hhs.gov/data/requests/cmsdua.pdf>.

**INSTRUCTIONS FOR COMPLETING THE DATA USE AGREEMENT (DUA)
AGREEMENT FOR USE OF CENTERS FOR MEDICARE
& MEDICAID SERVICES (CMS)
DATA CONTAINING INDIVIDUAL IDENTIFIERS**

This agreement is needed as part of the review of your data request to ensure compliance to the requirements of the Privacy Act, and must be completed prior to the release of specified data files containing individual identifiers. Directions for the completion of the agreement follow:

Before completing the DUA, please note the language contained in this agreement cannot be altered in any form.

- First paragraph, enter the Requestor's Organization Name.
- Item #1, enter the Requestor's Organization Name.
- Item #4, enter the Custodian Name, Company/Organization, Address, Phone Number (including area code), and E-Mail Address (if applicable). The Custodian of files is defined as that person who will have actual possession of and responsibility for the data files. This section should be completed even if the Custodian and Requestor are the same.
- Item #5 will be completed by a CMS representative.
- Item #6 is to be completed with the Study and or Project Name and a brief description of the purpose for which the file(s) will be used.
- Item #7 should delineate the files and years the Requestor is requesting. Specific file names should be completed. If these are unknown, you may contact a CMS representative.
- Item #8, complete by entering the Study/Project's date of completion.
- Item #15 will be completed by CMS.
- Item #19 is to be completed by Requestor.
- Item #20 is to be completed by Custodian.
- Item #21 will be completed by a CMS representative.
- Item #22 should be completed if your study is funded by another Federal Agency. The Federal Agency Name (Other than CMS) should be entered in the blank. The Federal Project Officer should complete and sign the remaining portions of this section. If this does not apply, leave blank.
- Item #23 will be completed by a CMS representative.

Once the DUA is received and reviewed for privacy issues, a completed and signed copy will be sent to the Requestor for their files.

AOD & HIPAA SAMPLE FORMS

The forms in this subsection integrate BOTH, the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule within 45 C.F.R. Parts 160 & 164 and the Alcohol and Other Drug (AOD) Confidentiality Rule within 42 C.F.R. Part 2. If you or your request is not governed by BOTH Federal laws, see the subsection above which applies to your situation

***REQUIRED DISCLAIMER:** To date, the sample form below is pending review and is NOT “Government approved”. Authorization has been given to distribute this draft form, as long as notice is provided to the recipient of the form that government review and approval status is currently pending. This sample form is created as a general aid for reference use only and does not constitute the rendering of legal or other professional advice by the Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, or its contractor, Social and Health Services, Ltd., a division of ORC Macro, Inc.*

**NOTICE OF PRIVACY PRACTICES &
CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE
PATIENT RECORDS**

Effective Date: _____

[Note that the effective date may not be earlier than the date on which the notice is printed or otherwise published!]

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.

Health information which we receive and/or create about you, personally, in this program, relating to your past, present, or future health, treatment, or payment for health care services, is “protected health information” under the Federal law known as the Health Insurance Portability and Accountability Act (HIPAA), 45 C.F.R. Parts 160 and 164. The confidentiality of alcohol and drug abuse patient records maintained by this program is protected by another Federal law as well, commonly referred to as the Alcohol and Other Drug (AOD) Confidentiality Law, 42 C.F.R. Part 2. Generally, the program may not say to a person outside the program that you attend the program, or disclose any information identifying you as an alcohol or drug abuser, or use or disclose any other protected health information except in limited circumstances as permitted by Federal law. Your health information is further protected by any pertinent state law that is more protective or stringent than either of these two Federal laws.

This Notice describes how we protect personal health information (otherwise referred to as “protected health information”) we have about you, and how we may use and disclose this information. This Notice also describes your rights with respect to protected health information and how you can exercise those rights.

Uses and disclosures that may be made of your health information:

• **Internal Communications:** Your protected health information will be used within our program, that is between and among program staff who have a need for the information, and between our program and _____ [state name of entity having administrative control of the program, if any], in connection with our duty to diagnose, treat, or refer you for substance abuse treatment. This means that your protected health information may be shared between or among personnel for treatment, payment or health care operation purposes. For example: Two or more providers within the program may consult with each other regarding your best course of treatment. The program and _____ [name any entity having administrative control over the program, if any] may share your protected health information in a billing effort to receive payment for health care services rendered to you. And/or, your protected health information may be discussed within the program about your treatment in connection with others in the program, in an effort to improve the overall quality of care provided by our program. Your protected health information will not be redisclosed by program personnel and/or _____ [state name of entity having administrative control of the program, if any], except as is otherwise permitted herein.

• **Qualified Service Organizations and/or Business Associates:** Some or all of your protected health information may be subject to disclosure through contracts for services with qualified service organizations and/or business associates, outside of this program, that assist our program in providing health care. Examples of qualified service organizations and/or business associates include billing companies, data processing companies, or companies that provide administrative or specialty services. To protect your health information, we require these qualified service organizations and/or business associates to follow the same standards held by this program through terms detailed in a written agreement.

• **Medical Emergencies:** Your health information may be disclosed to medical personnel in a medical emergency, when there is immediate threat to the health of an individual, and when immediate medical intervention is required.

• **To Researchers:** Under certain circumstances, this office may use and disclose your protected health information for research purposes. For example, a research project may involve comparing the health and recovery of all patients who received one test or treatment to those who received another, for the same condition. All research projects, however, must be approved by an Institutional Review Board, or other privacy review board as permitted within the regulations, that has reviewed the research proposal and established protocols to ensure the privacy of your protected health information.

• **To Auditors and Evaluators:** This program may disclose protected health information to regulatory agencies, funders, third-party payers, and peer review organizations that monitor alcohol and drug programs to ensure that the program is complying with regulatory mandates and is properly accounting for and disbursing funds received.

- **Authorizing Court Order:** This program may disclose your protected health information pursuant to an authorizing court order. This is a unique kind of court order in which certain application procedures have been taken to protect your identity, and in which the court makes certain specific determinations as outlined in the Federal regulations and limits the scope of the disclosure.
- **Crime on Program Premises or Against Program Personnel:** This program may disclose a limited amount of protected health information to law enforcement when a patient commits or threatens to commit a crime on the program premises or against program personnel.
- **Reporting Suspected Child Abuse and Neglect:** This program may report suspected child abuse or neglect as mandated by state law.
- **As Required By Law:** This program will disclose protected health information as required by state law in a manner otherwise permitted by federal privacy and confidentiality regulations.
- **Appointment Reminders:** This program reserves the right to contact you, in a manner permitted by law, with appointment reminders or information about treatment alternatives and other health related benefits that may be appropriate to you.
- **Other Uses and Disclosure of Protected Health Information:** Other uses and disclosures of protected health information not covered by this notice, will be made only with your written authorization or that of your legal representative. If you or your legal representative authorize us to use or disclose protected health information about you, you or your legal representative may revoke that authorization, at any time, except to the extent that we have already taken action relying on the authorization.

[Revise the above AOD protections to conform to more stringent protections provided by State law, if any.]

Your rights regarding protected health information we maintain about you:

- **Right to Inspect and Copy:** In most cases, you have the right to inspect and obtain a copy of the protected health information that we maintain about you. To inspect and copy your protected health information, you must submit your request in writing to this office. In order to receive a copy of your protected health information, you may be charged a fee for the photocopying, mailing, or other costs associated with your request. In some very limited circumstances we may, as authorized by law, deny your request to inspect and obtain a copy of your protected health information. You will be notified of a denial to any part or parts of your request. Some denials, by law, are reviewable, and you will be notified regarding the procedures for invoking a right to have a denial reviewed. Other denials, however, as set forth in the law, are not reviewable. Each

request will be reviewed individually, and a response will be provided to you in accordance with the law.

• **Right to Amend Your Protected Health Information:** If you believe that your protected health information is incorrect or that an important part of it is missing, you have the right to ask us to amend your protected health information while it is kept by or for us. You must provide your request and your reason for the request in writing, and submit it to this office. We may deny your request if it is not in writing or does not include a reason that supports the request. In addition, we may deny your request if you ask us to amend protected health information that we believe:

- Is accurate and complete;
- Was not created by us, unless the person or entity that created the protected health information is no longer available to make the amendment;
- Is not part of the protected health information kept by or for us; or
- Is not part of the protected health information which you would be permitted to inspect and copy.

If your right to amend is denied, we will notify you of the denial and provide you with instructions on how you may exercise your right to submit a written statement disagreeing with the denial and/or how you may request that your request to amend and a copy of the denial be kept together with the protected health information at issue, and disclosed together with any further disclosures of the protected health information at issue.

• **Right to an Accounting of Disclosures:** You have the right to request an accounting or list of the disclosures that we have made of protected health information about you. This list will not include certain disclosures as set forth in the HIPAA regulations, including those made for treatment, payment, or health care operations within our program and/or between our program and _____ [name any entity having administrative control over the program, if any], or made pursuant to your authorization or made directly to you. To request this list, you must submit your request in writing to this office. Your request must state the time period from which you want to receive a list of disclosures. The time period may not be longer than six years, and may not include dates before April 14, 2003. Your request should indicate in what form you want the list (for example, on paper or electronically). The first list you request within a 12-month period will be free. We may charge you for responding to any additional requests. We will notify you of the cost involved and you may choose to withdraw or modify your request at that time before any costs are incurred.

• **Right to Request Restrictions:** You have the right to request a restriction or limitation on protected health information we are permitted to use or disclose about you for treatment, payment or health care operations within our program and/or between our program and _____ [name any entity having administrative control over the program, if any]. While we will consider your request, **we are not required to agree to it.** If we do agree to it, we will comply with your request, except in emergency situations where your protected health information is

needed to provide you with emergency treatment. We will not agree to restrictions on uses or disclosures that are legally required, or those which are legally permitted and which we reasonably believe to be in the best interest of your health.

• **Right to Request Confidential Communications:** You have the right to request that we communicate with you about protected health information in a certain manner or at a certain location. For example, you can ask that we only contact you at work or by mail. To request confidential communications, you must make your request in writing to this office, and specify how or where you wish to be contacted. We will accommodate all reasonable requests.

• **Right to File a Complaint:** If you believe your privacy rights have been violated, you may file a complaint with this office or with the Secretary of the Department of Health and Human Services. To file a complaint with this office, please contact _____ [name, address, phone of your Privacy Officer, or other relevant instructions]. You will not be penalized or otherwise retaliated against for filing a complaint. If you have questions as to how to file a complaint please contact us at _____ [office name and address].

[Revise the above HIPAA patient rights to conform to more generous or stringent rights provided by State law, if any.]

Our responsibilities:

This office is required to:

- Maintain the privacy of your protected health information;
- Provide you with this notice of our legal duties and privacy practices with respect to your protected health information; and,
- Abide by the terms of this Notice while it is in effect.

This office reserves the right to change the terms of this Notice at any time and to make a new Notice with provisions effective for all protected health information that we maintain. In the event that changes are made, this office will notify you of a revised Notice by mail [or state other means of intended notification] at the current address provided on your medical file. [If applicable, this office will post changes on our Web site.]

To receive additional information:

For further explanation of this Notice you may contact _____ at _____ . [Fill in blanks with Privacy Official's name/title and telephone number and any other relevant contact information.]

Availability of Notice of Privacy Practices:

This notice will be posted where registration occurs [or whatever prominent location your office decides to post the notice]. You have a right to receive a copy of this notice, and all individuals receiving care will be given a hard copy. [If applicable to your practice you may include, “*This notice will be maintained and available for downloading at the following web site address: _____.*”]

Acknowledgement:

I hereby acknowledge that I received a copy of this Notice of Privacy Practices.

Patient Signature

Date

Source:

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**AUTHORIZATION FOR THE RELEASE OF
CONFIDENTIAL & PROTECTED HEALTH INFORMATION**

I, _____, authorize
(Name of patient)

(Name or general designation of program making disclosure)

to disclose to _____ the
(Name of person or organization to which disclosure is to be made)

following information: _____
(Specific nature of the information, as limited as possible)

The purpose of the disclosure authorized herein is to: _____
(Specific purpose of disclosure)

I understand that my records are protected under the Federal regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2, and that any information that identifies me as a patient in an alcohol or other drug abuse program cannot be disclosed without my written consent except in limited circumstances as provided for in these regulations.

I understand that my records are also currently protected under the Federal privacy regulations within the Health Insurance Portability and Accountability Act (HIPAA), 45 C.F.R. Parts 160 & 164. I understand that my health information specified above will be disclosed pursuant to this authorization, and that the recipient of the information may redisclose the information and it may no longer be protected by the HIPAA privacy law. The Federal regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2, noted above, however, will continue to protect the confidentiality of information that identifies me as a patient in an alcohol or other drug program from redisclosure.

I also understand that I may revoke this authorization at any time except to the extent that action has been taken in reliance on it, and that in any event this authorization expires automatically as follows:

(Specification of the date, event, or condition upon which this consent expires)

I understand that the covered entity seeking this authorization is not conditioning treatment, payment, enrollment or eligibility for benefits on whether I sign the authorization.

[OR, where conditioning is appropriate, substitute the above paragraph to state: I understand that the covered entity seeking this authorization is permitted under the HIPAA regulations, in accordance with 45 C.F.R. Section 164.508(b)(4), to condition my signing of this authorization on the provision of treatment, payment, enrollment or eligibility for benefits, and that by refusing to sign this authorization, I may be faced with the following consequences:

(State consequences)]

[If the authorization is for marketing purposes and Covered Entity may obtain remuneration, then add a paragraph to the authorization, such as:

This authorization is for the use and/or disclosure of protected health information for marketing purposes, and the covered entity seeking this authorization will obtain direct or indirect remuneration from a third party in this regard.]

DRAFT: FOR EXAMPLE PURPOSES ONLY

I understand that I am entitled to receive a copy of this authorization after it is signed.

Dated: _____

Signature of patient

Signature of parent, guardian or authorized
representative, when required

Source:

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READ THIS NOTICE BEFORE USING THIS FORM!!!

NOTICE: In lieu of this form, court orders can be used to comply with HIPAA, along with continued use of the irrevocable consent form that otherwise complies with the regulations within 42 C.F.R. Part 2. This sample/draft form can be considered where there is a preference to use an authorization form that complies with both 42 CFR Part 2 and the HIPAA privacy provisions. However, this sample/draft form is for drug court programs that are not themselves regulated by HIPAA, but which include within the drug court team a treatment provider/agency that is a HIPAA covered entity. ***In the possible but rare instance in which the drug court program itself is regulated by HIPAA, this form should not be used without further specific guidance in this regard by the Department of Health and Human Service/Office for Civil Rights, and the court order option should instead be considered in order to comply with HIPAA.***

**AUTHORIZATION FOR DISCLOSURE OF CONFIDENTIAL
SUBSTANCE ABUSE INFORMATION: DRUG COURT REFERRAL**

I, _____, hereby authorize communication between _____
(Name of Defendant) (Name of Treatment Program)

and Judge _____, _____,
(Name of Presiding Judge, Drug Court Judge) (Prosecuting Attorney, Assistant Prosecuting Attorney)

_____, the probation department of _____,
(Defense Counsel) (Name of Jurisdiction)

and _____.
(Name(s) of other agencies, as applicable)

The purpose of, and need for, this disclosure is to inform the court and all other named parties of my eligibility and/or acceptability for substance abuse treatment services and my treatment attendance, prognosis, compliance and progress in accordance with the drug treatment court

program's monitoring criteria. The type and extent of the information to be disclosed will include only that information which is necessary for, and pertinent to, the drug court program's monitoring criteria in connection with the case/charges noted below.

Disclosure of this confidential information may be made only as necessary for, and pertinent to, hearings and/or reports concerning:

(List charges, docket number and indictment number)

I understand that such information, where necessary, will be disclosed in open-court, which is a public forum, and I hereby authorize the same.

I understand that my records are protected under the Federal regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2, and that any information that identifies me as a patient in an alcohol or other drug abuse program cannot be disclosed without my written consent except in limited circumstances as provided for in these regulations. I also understand that recipients of this information may redisclose it only on connection with their official duties.

I also understand that my records are also currently protected under the Federal privacy regulations within the Health Insurance Portability and Accountability Act (HIPAA), 45 C.F.R. Parts 160 & 164. I understand that my health information specified above will be disclosed pursuant to this authorization, and that the recipient of the information may redisclose the information and it may no longer be protected by the HIPAA privacy law. The Federal regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2, noted above, however, will continue to protect the confidentiality of information that identifies me as a patient in an alcohol or other drug program.

I understand the covered entity (alcohol or other drug abuse treatment provider) is not conditioning treatment, payment, enrollment, or eligibility for benefits on whether I sign this authorization.

I also understand that I may revoke this authorization at any time except to the extent that action has been taken in reliance on it, and that in any event this authorization will expire automatically when there has been a formal and effective termination of my involvement with the drug court program for the above-referenced case, such as the discontinuation of all court (and/or, where relevant, probation) supervision upon my successful completion of the drug court requirements, OR upon sentencing for violating the terms of my drug court involvement (and/or, where relevant, probation).

I understand that if I revoke this authorization prior to successful completion of all requirements within the drug court program, it may result in the drug court terminating me from participation in the drug court program.

DRAFT: FOR EXAMPLE PURPOSES ONLY

(Date)

(Name)

(Signature)

(Signature of Defense Counsel)

(Signature of Interpreter – where applicable)

(Signature of parent or guardian – where applicable)

Source:
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***REQUIRED DISCLAIMER:** To date, the sample form below is pending review and is NOT “Government approved”. Authorization has been given to distribute this draft form, as long as notice is provided to the recipient of the form that government review and approval status is currently pending. This sample form is created as a general aid for reference use only and does not constitute the rendering of legal or other professional advice by the Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, or its contractor, Social and Health Services, Ltd., a division of ORC Macro, Inc.*

QUALIFIED SERVICE ORGANIZATION/BUSINESS ASSOCIATE AGREEMENT

This Qualified Service Organization/Business Associate Agreement (“QSO-BA Agreement”) is entered into on this _____ day of _____, 20____, by and between _____ and _____.

(Covered Entity) (Qualified Service Organization/Business Associate)

Recitals

- A. Covered Entity will make available and/or provide certain Protected Health Information (as defined below) to Qualified Service Organization/Business Associate in the course of the parties’ relationship.
- B. In order to protect the privacy of the Protected Health Information and to comply with HIPAA and the HIPAA Regulations (as defined below), Covered Entity and Qualified Service Organization/Business Associate desire to enter into this QSO-BA Agreement setting forth the terms and conditions of use and disclosure of Protected Health Information.

In consideration of the mutual promises set forth below, the parties agree as follows:

Article 1: Definitions

- 1.1 **Qualified Service Organization/Business Associate.** “Qualified Service Organization/Business Associate” shall mean [Insert name of Qualified Service Organization/Business Associate].
- 1.2 **Covered Entity.** “Covered Entity” shall mean [Insert name of Covered Program].

- 1.3 **Individual.** “Individual” shall have the same meaning as the term “individual” in 45 CFR § 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 CFR § 164.502(g).
- 1.4 **HIPAA.** “HIPAA” means the Health Insurance Portability & Accountability Act of 1996, P.L. 104-91.
- 1.5 **HIPAA Regulations.** “HIPAA Regulations” mean the regulations promulgated under HIPAA by the U.S. Department of Health and Human Services, including the Privacy Rule.
- 1.6 **Privacy Rule.** “Privacy Rule” shall mean the Standards for Privacy of Individually Identifiable Health Information in 45 CFR Part 160 and Part 164, Subparts A and E.
- 1.7 **Protected Health Information.** “Protected Health Information” shall have the same meaning as the term “protected health information” in 45 CFR § 164.501, limited to the information created or received by Qualified Service Organization/Business Associate from or on behalf of the Covered Entity.
- 1.8 **Secretary.** “Secretary” shall mean the Secretary of the Department of Health and Human Services or the Secretary’s designee.
- 1.9 **General Rule.** Capitalized terms not otherwise defined in this QSO-BA Agreement shall have the same meaning as those terms in the HIPAA Regulations.

**Article 2: Obligations and Activities of
Qualified Service Organization/Business Associate**

- 2.1 **Acknowledgement of Applicable Federal Laws.** Qualified Service Organization/Business Associate acknowledges that in receiving, storing, processing, or otherwise dealing with any information from the Covered Entity about the patients in the Covered Entity, it is fully bound by the provisions of the Federal regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 CFR Part 2 AND by HIPAA.
- 2.2 **Protecting & Resisting Access.** Qualified Service Organization/Business Associate agrees to resist in judicial proceedings any effort to obtain access to information pertaining to patients otherwise than as expressly provided for in the Federal regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 CFR Part 2.

- 2.3 **Prohibitions.** Qualified Service Organization/Business Associate agrees to not use or disclose Protected Health Information other than as permitted or required by the QSO-BA Agreement.
- 2.4 **Safeguards.** Qualified Service Organization/Business Associate agrees to implement and use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this QSO-BA Agreement.
- 2.5 **Mitigation.** Qualified Service Organization/Business Associate agrees to mitigate promptly, to the extent practicable, any harmful effect that is known to Qualified Service Organization/Business Associate of a use or disclosure of Protected Health Information by Qualified Service Organization/Business Associate in violation of the QSO-BA Agreement, the Privacy Rule, or other applicable federal or state law.
- 2.6 **Reports of Improper Use or Disclosure.** Qualified Service Organization/Business Associate agrees to immediately report to Covered Entity any use or disclosure of the Protected Health Information not provided for by this QSO-BA Agreement of which it becomes aware. Qualified Service Organization/Business Associate also agrees to immediately report to Covered Entity about any complaint that the Qualified Service Organization/Business Associate receives concerning the handling of Protected Health Information or compliance with this QSO-BA Agreement.
- 2.7 **Disclosures to Agents and Subcontractors, if permitted by law.** If the Qualified Service Organization/Business Associate intends to provide Protected Health Information to any agent or subcontractor, it must first obtain written, legal assurances that such disclosure of Protected Health Information would not violate any provisions of the Alcohol and Other Drug (AOD) Confidentiality law within 42 C.F.R. Part 2 and/or any other applicable federal or state laws, and such assurances must be provided to and accepted by the Covered Entity. If such written assurances are obtained and if they are accepted by the Covered Entity, after having an opportunity to consult with independent counsel, Qualified Service Organization/Business Associate further agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by Qualified Service Organization/Business Associate on behalf of Covered Entity agrees to the same restrictions and conditions that apply through this Agreement to Qualified Service Organization/Business Associate with respect to such information.

[Note: The Alcohol and Other Drug Confidentiality law, 42 CFR Part 2, prohibits a qualified service organization from redisclosing any patient identifiable information it may obtain in the course of an agreement, except as otherwise permitted by that federal regulation. So, it would appear that a qualified service organization would not be permitted to redisclose patient identifiable information to an agent or subcontractor, as would otherwise be permitted under HIPAA. The HIPAA Privacy regulations require that some form of the second sentence in the above paragraph be included in a business associate agreement. No clear guidance has been provided to date on this point from the Department of Health and Human Services or its enforcement arm, the Office for Civil Rights. This paragraph is one potential way to

address this concern. The parties should discuss this issue, and if the qualified service organization/business associate wants to bring in an agent or subcontractor, obtain independent legal counsel to ensure that doing so will not be a violation of the law.]

- 2.8 **Access.** To enable the Covered Entity to fulfill its obligations under the Privacy Rule, Qualified Service Organization/Business Associate agrees to make Protected Health Information in Designated Record Sets that are maintained by Qualified Service Organization/Business Associates or its agents or subcontractors available to Covered Entity for inspection and copying within ten (10) days of a request by Covered Entity. If an Individual requests inspection and copying of Protected Health Information directly from Qualified Service Organization/Business Associate or its agents or subcontractors, Qualified Service Organization/Business Associate shall notify the Covered Entity in writing within five (5) business days of receipt of the request, and shall defer to, and comply with, Covered Entity's direction in a timely manner regarding the response to the Individual regarding the request for inspection and copying.

[This is an example. The specific terms outlined in this paragraph should accurately reflect the agreed upon terms following discussions and negotiations between the parties.]

- 2.9 **Amendment.** To enable the Covered Entity to fulfill its obligations under the Privacy Rule, Qualified Service Organization/Business Associate agrees to make any amendment(s) to Protected Health Information in a Designated Record Set that are maintained by Qualified Service Organization/Business Associate or its agents or subcontractors that the Covered Entity directs or agrees to pursuant to 45 CFR § 164 within ten (10) days of a request by Covered Entity. If an Individual requests amendment of Protected Health Information directly from Qualified Service Organization/Business Associate or its agents or subcontractors, Qualified Service Organization/Business Associate shall notify the Covered Entity in writing within five (5) business days of receipt of the request, and shall defer to, and comply with, Covered Entity's direction in a timely manner regarding the response to the Individual regarding the request for amendment.

[This is an example. The specific terms outlined in this paragraph should accurately reflect the agreed upon terms following discussions and negotiations between the parties.]

- 2.10 **Federal Government Officials.** Qualified Service Organization/Business Associate agrees to make internal practices, books, and records, including policies and procedures and Protected Health Information, relating to the use and disclosure of Protected Health Information received from, or created or received by Qualified Service Organization/Business Associate on behalf of, Covered Entity available to the Secretary as designated by the Secretary, for purposes of the Secretary determining Covered Entity's compliance with the Privacy Rule. Qualified Service Organization/Business Associate shall notify Covered Entity regarding any Protected Health Information that Qualified Service Organization/Business Associate provides to the Secretary concurrently

with providing such Protected Health Information to the Secretary, and upon Covered Entity's request, shall provide Covered Entity with a duplicate copy of such Protected Health Information.

[This is an example. The specific terms outlined in this paragraph should accurately reflect the agreed upon terms following discussions and negotiations between the parties.]

2.11 **Documentation of Disclosures.** Qualified Service Organization/Business Associate agrees to implement a process for documenting such disclosures of Protected Health Information and information related to such disclosures as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR § 164.528.

2.12 **Accounting of Disclosures.** Qualified Service Organization/Business Associate agrees to provide to Covered Entity the information collected in accordance with Section 2.11 of this QSO-BA Agreement within ten (10) days of the Covered Entity's request in order to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR § 164.528. If an individual requests an accounting directly from Qualified Service Organization/Business Associate or its agents or subcontractors, Qualified Service Organization/Business Associate must notify Covered Entity in writing within five (5) business days of the request, and shall defer to, and comply in a timely manner with, Covered Entity's direction regarding the response to the Individual regarding the request for an accounting.

[This is an example. The specific terms outlined in this paragraph should accurately reflect the agreed upon terms following discussions and negotiations between the parties.]

**Article 3: Permitted Uses and Disclosures by
Qualified Service Organization/Business Associate**

3.1 **Specific Purposes.** Except as otherwise limited in this QSO-BA Agreement, Qualified Service Organization/Business Associate may use or disclose Protected Health Information on behalf of, or to provide services to, Covered Entity for the following purposes, provided that such use or disclosure of Protected Health Information would not violate the Privacy Rule or the Alcohol and Drug Confidentiality law within 42 C.F.R. Part 2 if done by Covered Entity or the minimum necessary policies and procedures of the Covered Entity:

[List purposes]

[An alternative approach to listing specific purposes in the body of this QSO-BA Agreement is to refer to an underlying services agreement which otherwise states the purposes. For example:

Except as otherwise limited in this QSO-BA Agreement, Qualified Service Organization/Business Associate may use or disclose Protected Health Information to perform the functions, activities, or services for, or on behalf of, Covered Entity as specified in Exhibit A, attached hereto and incorporated herein, provided that such Use or Disclosure would not violated the Privacy Rule if done by Covered Entity or the minimum necessary policies and procedures of the Covered Entity.

If this alternative approach is used, remember to label and attach as part of the QSO-BA Agreement an “Exhibit A” in this regard.]

Article 4: Obligations of Covered Entity

- 4.1 **Notice of Privacy Practices.** Covered Entity shall notify Qualified Service Organization/Business Associate of any limitation(s) in its notice of privacy practices of Covered Entity in accordance with 45 CFR § 164.520, to the extent that such limitation may affect Qualified Service Organization/Business Associate’s use or disclosure of Protected Health Information.
- 4.2 **Individual Permission.** Covered Entity shall notify Qualified Service Organization/Business Associate of any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, to the extent that such changes may affect Qualified Service Organization/Business Associate’s use or disclosure of Protected Health Information.
- 4.3 **Restrictions.** Covered Entity shall notify Qualified Service Organization/Business Associate of any restriction to the use or disclosure of Protected Health Information that Covered Entity has agreed to in accordance with 45 CFR § 164.522, to the extent that such restriction may affect Qualified Service Organization/Business Associate’s use or disclosure of Protected Health Information.
- 4.4 **Prohibited Requests.** Covered Entity shall not request Qualified Service Organization/Business Associate to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule if done by Covered Entity. This provision does not otherwise affect the Qualified Service Organization/Business Associate’s permitted use and disclosure of Protected Health Information for data aggregation (permitted in 3.4 above) and/or management and administrative activities (permitted in 3.3 above).

Article 5: Term and Termination

5.1 **Term.** The Term of this QSO-BA Agreement shall be effective as of _____, and shall terminate when all of the Protected Health Information provided by Covered Entity to Qualified Service Organization/Business Associate, or created or received by Qualified Service Organization/Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity, or, if it is infeasible to return or destroy Protected Health Information, protections are extended to such information, in accordance with the termination provisions in this Section.

[Note: Term may differ, and should accurately reflect the agreed upon terms following discussions and negotiations between the parties.]

5.2 **Termination for Cause.** Upon Covered Entity's knowledge of a material breach by Qualified Service Organization/Business Associate, Covered Entity shall either:

- A. Provide an opportunity for Qualified Service Organization/Business Associate to cure the breach or end the violation, and terminate this Agreement if Qualified Service Organization/Business Associate does not cure the breach or end the violation within the time specified by Covered Entity;
- B. Immediately terminate this Agreement if Qualified Service Organization/Business Associate has breached a material term of this Agreement and cure is not possible; or
- C. If neither termination nor cure is feasible, Covered Entity shall report the violation to the Secretary.

[Note that the opportunity to cure is permitted, but not required by the Privacy Rule. The above paragraphs can be replaced with: "A. Immediately terminate this QSO-BA Agreement if Qualified Service Organization/Business Associate has breached a material term of this QSO-BA Agreement", and "B. If neither termination are feasible, Covered Entity shall report the violation to the Secretary."]

5.3 **Effect of Termination.**

- A. Except as provided in paragraph (B) of this section, upon termination of this Agreement, for any reason, Qualified Service Organization/Business Associate shall return or destroy all Protected Health Information received from Covered Entity, or created or received by Qualified Service Organization/Business Associate on behalf of Covered Entity. This provision shall apply to Protected

Health Information that is in the possession of subcontractors or agents of Qualified Service Organization/Business Associate. Qualified Service Organization/Business Associate shall retain no copies of the Protected Health Information.

- B. In the event that Qualified Service Organization/Business Associate determines that returning or destroying the Protected Health Information is infeasible, Qualified Service Organization/Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction infeasible. Qualified Service Organization/Business Associate shall thereafter extend the protections of this Agreement to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Qualified Service Organization/Business Associate maintains such Protected Health Information.

- 5.4 **Survival.** The respective rights and obligations of Qualified Service Organization/Business Associate under this Article 5 shall survive the termination of this QSO-BA Agreement.

Article 6: Miscellaneous

- 6.1 **Regulatory References.** A reference in this Agreement to a section in the Privacy Rule means the section as in effect or as amended.
- 6.2 **Amendment.** The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the Privacy Rule and the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191 and/or the Alcohol and Drug Confidentiality law within 42 C.F.R. Part 2.
- 6.3 **Interpretation.** Any ambiguity in this QSO-BA Agreement shall be resolved to permit Covered Entity to comply with the Privacy Rule.
- 6.4 **State Law.** In addition to HIPAA and the HIPAA Regulations and the Alcohol and Drug Confidentiality law within 42 C.F.R. Part 2, Qualified Service Organization/Business Associate shall comply with all applicable state and federal privacy and security laws.

6.5 **Notices.** Under the terms of this QSO-BA Agreement, either party shall be deemed as being given notice, if delivered personally, or if mailed by first class United States mail, postage prepaid, and addressed as follows:

If to Covered Entity:

If to Qualified Service Organization/
Business Associate:

Attention:_____

Attention:_____

[State full addresses and name contact persons.]

[This is an example. The method of notification outlined in this paragraph should accurately reflect the negotiations and agreed upon terms between the parties.]

6.6 **Notification of Change of Address.** If Covered Entity and/or Qualified Service Organization/Business Associate change its address for notification purposes, it shall promptly notify the other party to this QSO-BA Agreement in writing and clearly state the new address and the effective date for the change of address.

6.7 **Good Faith.** The parties to this QSO-BA Agreement agree to exercise good faith in the performance of this contract.

6.8 **Attorneys Fees.** Each party to this QSO-BA Agreement agrees to bear its own legal expenses and any other cost incurred for actions or proceedings brought about by the enforcement of this contract, or from an alleged dispute, breach, default, misrepresentation, or injunctive action associated with the provisions of this contract.

[Another, alternative option would be to require the Qualified Service Organization/Business Associate to maintain insurance coverage for itself and its agents and subcontractors against any claim or claims for damages that arise under this QSO-BA Agreement. And, to require the Qualified Service Organization/Business Associate to indemnify, hold harmless, and defend Covered Entity from and against any and all claims, losses, liabilities, costs, and other expenses, including reasonable attorneys fees and costs, incurred as a result of, or arising out of any act or omission of Qualified Service Organization/Business Associate, its agents or subcontractors, under this QSO-BA Agreement.]

6.9 **Disputes.** Any controversy or claim arising from or relating to the terms defined under this contract are subject to settlement by compulsory arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association, except for

injunctive relief which may be sought by the Covered Entity to prevent or stop the unauthorized use or disclosure of information by Qualified Service Organization/Business Associate or any agent, contractor, or third party that received information from Qualified Service Organization/Business Associate.

[This is one option, but it really depends on negotiations. Compulsory arbitration may not be desired or agreed to by the parties. This paragraph may be left out or altered to conform to the agreed upon terms of the parties following discussions and negotiations.]

6.10 **Entire Agreement.** This QSO-BA Agreement sets forth the entire agreement between the Covered Entity and Qualified Service Organization/Business Associate. The terms of this contract shall be binding on the parties. Neither party has the authority to reassign this agreement without the other's written consent.

[Note: Any other agreements made between the parties following negotiations that are not otherwise set forth above in this QSO-BA Agreement should be inserted so that this agreement clearly reflects the entire agreement of the parties. Also, be sure to include any other or additional provisions required by your respective state law.]

IN WITNESS WHEREOF, the parties hereto have duly executed this QSO-BA Agreement as of the date set forth in the first paragraph of this agreement.

**QUALIFIED SERVICE ORGANIZATION/
BUSINESS ASSOCIATE:**

COVERED ENTITY:

Signature

Signature

Print Name

Print Name

Title

Title

Source:

This sample form was drafted by Social and Health Services, Ltd., a division of ORC Macro.