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HIPAA's Applicability To and Impact On The Drug and Alcohol Testing Industry - A Position Paper -

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HIPAA Does Not Apply To The Drug and Alcohol Testing Industry

Introduction

There is currently some debate as to whether the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and its implementing Regulations apply to non-regulated drug and alcohol tests, pre-placement physicals, and fitness-for-duty examinations. Fundamental rules of statutory and regulatory construction require that those covered by a statute or regulation be clearly notified that they are covered and be advised of any affirmative legal duties they may have. These fundamental rules are not fulfilled by HIPAA's plain language as it relates to the Drug and Alcohol Testing Industry. Therefore, HIPAA does not apply.

Until HIPAA and its implementing Regulations are clarified by amendment, the Drug and Alcohol Testing Service Industry has no legal duty to comply with HIPAA's requirements. Over time, voluntary compliance with HIPAA would result in the Drug and Alcohol Testing Industry's transformation into a health care industry provider. This is not prudent because the Drug and Alcohol Testing Industry will then become subject to the challenges and issues confronting the Health Care Industry. These challenges and issues are in part why HIPAA was necessary for the Health Care Industry to begin with.

Discussion

Non-Regulated/Non-Mandated Drug and Alcohol Testing, Pre-Placement Physicals and Fitness-For-Duty Examinations are all workplace qualification strategies or safety and security related employer tools. All are forensic tests, not medical tests, and are not health related. When such strategies and tools are considered Protected Health Information (PHI) and therefore subject to HIPAA and its implementing Regulations, a chilling effect on the safety, security and economic benefits of such activities will likely result. This is due to the onerous additional affirmative legal duties that HIPAA would impose on an industry that has not been part of the Health Care Industry.

This chilling effect also raises serious public policy concerns for a Nation actively engaged in a War against Drugs. Substance abuse and alcohol misuse can alter an individual's judgment and negatively impact an individual's safety and security as well as the safety and security of others in the workplace.

For public policy reasons, a swift and timely resolution of HIPAA's applicability to Non-Regulated/Non-Mandated Drug and Alcohol Testing, Pre-Placement Physicals, and Fitness-For-Duty Examinations is critically important. Absent resolution in the very near future, reality is likely to be socially constructed over time by Drug and Alcohol Industry Service Agent/providers who elect to comply with HIPAA out of fear of non-compliance enforcement sanctions, legal exposure risks or under pressure from the employers they serve.

Historical Summary

HIPAA originally was passed because of congressional concerns about the transferability and portability of employees' health coverage. HIPAA pertains to the transmission of health care information in electronic form as well as maintaining the security and privacy of health information. As the health care industry utilized electronic data interchange (EDI) on a more widespread basis, it realized that the health care system overall was not reaching the efficiencies that should have resulted from this technological advance. In order to increase the efficiency, effectiveness, and cost savings through the use of electronic data interchange in the health care industry, Congress passed legislation that requires all health care providers, health care clearinghouses, and health plans to implement and utilize standardized formats when transmitting electronic data. This standardization was meant to ensure that all providers and health plans transmit and receive health care information using the same formats, code sets and data elements. This was conceived as a "behind the scenes" effort that would require software and system upgrades and adjustments. As a result of the increased use of electronic data interchange, Congress also realized that additional privacy and security measures would be needed. Congress therefore mandated that health care providers implement security measures to protect patient health care information that is stored and transmitted electronically, as well as implement additional safeguards to protect health care information that is maintained on paper and other mediums. Regarding the "portability" of an employee's health coverage, HIPAA was concerned about protecting an employee from being denied health coverage unjustly should the employee relocate or change employers.

HHS Fact Sheet dated August 22, 2002 published by the U.S. Department of Health and Human Services specifically outlined the purpose and scope of HIPAA as follows:

ADMINISTRATIVE SIMPLIFICATION UNDER HIPAA:
NATIONAL STANDARDS FOR TRANSACTIONS, SECURITY AND PRIVACY

To improve the efficiency and effectiveness of the health care system, the Health Insurance Portability and Accountability Act (HIPAA) of 1996 included a series of "administrative simplification" provisions that required the Department of Health and Human Services (HHS) to adopt national standards for electronic health transactions. By ensuring consistency throughout the industry, these national standards will make it easier for health plans, doctors, hospitals and other health care providers to process claims and other transactions electronically. The law also requires the adoption of security and privacy standards in order to protect personal health information. HHS is issuing the following regulations:

- **Electronic health care transactions (final rule issued);**
- **Health information privacy (final rule issued);**
- **Unique identifier for employers (final rule issued);**
- **Security requirements (final rule issued);**
- **Unique identifier for providers (proposed rule issued; final rule in development);**
- **Unique identifier for health plans (proposed rule in development); and**
- **Enforcement procedures (preliminary proposed rule issued).**

Although the HIPAA law also called for a unique health identifier for individuals, HHS and Congress have indefinitely postponed any effort to develop such a standard.

Under HIPAA, most health plans, health care clearinghouses and health care providers who engage in certain electronic transactions have two years from the time the final regulations takes effect to implement each set of final standards. On August 14, 2002, the Final Modifications to the Privacy Rule were published in the Federal Register at Volume 67, Number 157 pages 53181-53273. More information about HIPAA standards is available at: http://asp.hhs.gov/admnsimp/ and http://www.cms.gov/hipaa.

The compliance date for the Privacy Rule was April 14, 2003 for most covered entities (certain health care providers, health plans, and health care clearinghouses). Small health plans have until April 14, 2004 to comply.

Analysis

There are three parts to an analysis of HIPAA as it relates to the Drug and Alcohol Testing Industry. They are 1) the "covered entity" determination, 2) an examination of health information under HIPAA and whether Drug and Alcohol Testing Industry Service Agents handle "Protected Health Information" (PHI) as defined by HIPAA and 3) a review of the negative impact HIPAA compliance could have on the Drug and Alcohol Testing Industry.

1. Covered Entity Analysis

Service Agents in the Drug and Alcohol Testing Industry include Consortium/Third Party Administrators (C/TPAs), Collectors, Alcohol Testing Personnel (Breath Alcohol Technicians (BATs) and Screening Test Technicians (STTs)), Medical Review Officers and Substance Abuse Professionals. The two pronged inquiry for coverage determination for such Service Agents businesses and individuals are 1) whether they are "covered entities" under HIPAA and 2) whether the services Industry Service Agents provide are health related or forensic, safety and security related and/or qualification determining related services. Drug Alcohol Testing Industry Service Agents are not covered entities under HIPAA's criteria defining covered entities. Secondly, the services they provide employers are forensic tools, qualification determining, safety and security related, not health related and do not result in the generation of protected health information (PHI). Because Industry Service Agents do not provide health related services generating PHI, HIPAA does not apply to such services and the information generated thereby.

The Center for Medicare & Medicaid Services' HIPAA electronic Covered Entity Decision Support Tool guides a possible covered entity through its coverage decision analysis by posing four coverage questions. Those four questions are as follows:

- Is a Person, Business, or Agency a Covered Health Care Provider? *Does the person, business or agency furnish, bill or receive payment for **health care** in the normal course of business? (Bolding added)*
- Is a Business or Agency Health Care Clearinghouse? *Does the business or agency process, or facilitate the processing of, **health** information from standard format content into nonstandard format or content? (Bolding added)*
- Is a Government Funded Program a **Health Plan**? *Is the program one of the listed government health plans? (Bolding added)*
- Is a Private Benefit Plan a **Health Plan**? *Is the plan an individual or group plan, or combination thereof, that provides, or pays for the cost of medical care? (Bolding added)*

http://www.cms.gov/hipaa/hippa2/support/tools/decisionsuppdecision=D1

Service Agents in the Drug and Alcohol Testing Industry do not meet any of the threshold tests used to determine HIPAA coverage because Industry Service Agents **simply do not provide health services.**

The remaining coverage issues to analyze are whether Drug and Alcohol Testing Service Agents are "Hybrid" covered entities or are brought into HIPAA under the Business Associate requirements. They are neither of these because they **are not** covered entities when performing the services the Industry offers and **do not** provide or support health care services provided by other health care providers.

2. Health Information Under HIPAA

Under HIPAA Health Care means:

Care, services or supplies related to the health of an individual. It includes, but is not limited to, the following:

(1) Preventive, diagnostic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition or functional status, of an individual or that affects the structure or function of the body; (2) Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription. 45 CFR 160.103.

None of the services provided by the Drug and Alcohol Testing Industry meet the foregoing definition.

As the Department of Transportation Office of the Secretary of Transportation, Office of Drug and Alcohol Policy and Compliance astutely and clearly points out in pertinent part in its General Issue 5/03 Answer interpreting HIPAA for the DOT Drug and Alcohol Testing Programs:

DOT-required drug and alcohol testing information differs significantly from health information covered by HIPAA rules (45 CFR Part 164). The DOT program is concerned only with employees' compliance with DOT safety regulations, and not with preventive, diagnostic, therapeutic, rehabilitative maintenance, or palliative care or the past, present, or future physical or mental health or condition of an individual.

Non-DOT, Non-Mandated/Non-Regulated Drug and Alcohol Testing generally mirrors the DOT's gold standard for testing and the information processed also differs significantly from health information covered by HIPAA rules (45 CFR Part 164). The purpose of Non-Mandated Drug and Alcohol Testing is to maintain workforce qualification standards and to protect the safety and security of the workforce. The purpose and use for the information has nothing whatsoever to do with the main purpose and intent of HIPAA, which is health insurance accountability and portability. The very same argument can be made for Pre-Placement Physicals and Fitness-For-Duty Examinations. These tests are structurally the same as federally mandated qualifying physicals and examinations, such as Federal Motor Carrier Safety Administration DOT Physical Examinations.

Furthermore, Drug and Alcohol Testing Industry Service Agents do not handle Protected Health Information (PHI) as defined by HIPAA. Protected Health Information (PHI) includes information that relates to preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, or the past, present, or future physical or mental health of an individual. HIPAA's requirements were designed to protect such confidential information from being transferred and/or used without authorization or consent in the context of the Act's mission, purpose and intent. The services provided by the Drug and Alcohol Testing Industry simply does not fall within HIPAA's mission and intent.

The information that the Drug and Alcohol Testing Industry handles is not medical information and does not fall into HIPAA's broad definition of protected health information. The services the Industry provides are not intended to diagnose a disease or medical condition of a patient. Nor do they have medical, diagnostic or treatment purposes.

3. Negative Impact of HIPAA Compliance

HIPAA compliance is not just a matter of complying with a Consent/Authorization for the release of Protected Health Information (PHI) requirement. It includes numerous other affirmative duties as well. Among these duties are promulgating notices and policies, educating and training on HIPAA, and possibly additional electronic transmission and security related responsibilities. Also, should the Drug and Alcohol Testing Industry be perceived to be part of the Health Care Industry it may be subject to unexpected additional Health Care Industry related affirmative legal and regulatory responsibilities, the scope of which is possibly more than can be reasonably anticipated or predicted. Just one example of additional responsibilities is the State Health Care Privacy Laws. If the Industry becomes part of the Health Care Industry courtesy of HIPAA, the State Health Care Privacy Laws may suddenly apply as well.

There will also be additional operational and procedural burdens to the Drug and Alcohol Testing Industry, the clients it serves and the vendors it does business with. Some of these operational and procedural burdens may have a negative impact on DOT and federal government testing programs because they will create more confusion between the two programs. Consents/Authorizations will likely be obtained in error for federally regulated tests when various players in the service delivery system attempt to comply with HIPAA. This will certainly undermine the Department of Transportation Testing Programs and increase procedurally based litigation.

As procedural/operational burdens increase service delivery costs and litigation costs will increase proportionally. Both could be a disincentive to employers and result in a negative impact on the War on Drugs and undermine the gains that the Drug and Alcohol Testing Industry has achieved thus far.

Conclusion

The Drug and Alcohol Testing Industry **must not** give in to a perception of HIPAA coverage based on fear of non-compliance enforcement, legal exposure risk or client pressure. Rather, if Congress meant to include the Drug and Alcohol Industry, the Industry should wait for Congress to properly amend the Health Insurance Portability and Accountability Act to provide the Industry with adequate notice in plain and clear language that the Industry is covered by HIPAA and what exactly the Industry’s affirmative obligations include.