

Internal Audit, Anti-Fraud

Compliance and Ethics Conference

Non-Discriminating Tastes Family History, GINA, and You

**Blue Cross Blue
Shield Association**

May 18-20, 2010
New Orleans, LA

Thomas D. Bixby
Law Office LLC
(608) 661-4310
TBixby@tbixbylaw.com

Topics

- **Background & Application**
- **Genetic Information**
- **Use for Premium Rating**
- **Genetic Testing**
- **Collection Prior to Enrollment**
- **Collection for “Underwriting”**
- **The Individual Market**
- **Privacy Rule & Notices**

Background & Application

▪ Genetic Information Nondiscrimination Act of 2008

Title I

- Prohibits discrimination in health coverage
- New Privacy protections

Title II

- Prohibits discrimination in employment

Background & Application

HHS

Centers for
Medicare &
Medicaid
Services

DOL

Employee
Benefits
Security
Administration

Treasury

Internal
Revenue
Service

Background & Application

HHS/CMS

45 C.F.R.
Parts 144,
146, 148

DOL/EBSA

29 C.F.R.
Part 2590

Treasury/IRS

26 C.F.R.
Part 54

Background & Application

**Statute effective
plan years
beginning 5/21/09**

**GINA Rules
effective plan years
beginning 12/7/09**

- Implementation issues arising from broad interpretation of statute

Background & Application

GINA applies to

- Group insurance coverage
- Individual insurance coverage
- Group health plans—ERISA & non-ERISA
- Government plans—no opt out
- Medigap issuers

Genetic Information

Includes:

- Genetic tests (of individual or family)
- Request for genetic services

Includes:

- *Family member's manifestation of disease or disorder*

Excludes:

- Information about gender
- Information about age

Manifestation of disease or disorder

- Has been diagnosed
- By health care professional
- With appropriate training and expertise
- Not based primarily on genetic information

Genetic Information

Individual's manifestation

- Not genetic information about the individual
- Treatment arising from genetic information

Family member's manifestation

- Genetic information about the individual

Premium Rating

Prohibits use of genetic information for premium rating

- Group insurance coverage
- Individual insurance coverage
- Individual contributions to group plan

Rule of Construction

- May use manifested disease or disorder

Premium Rating

**Application to
family/group
coverage:**

- Father's diagnosed diabetes
 - May use to “rate up” father
 - Cannot use to rate up children

Genetic Tests

May not request or require genetic tests

Exceptions

- Health care professional
- Determination of Payment
- Research

Prior to Enrollment

**Cannot
collect
genetic
infor-
mation:**

- Prior to enrollment
- In connection with rules for eligibility

Prior to Enrollment

Rules for eligibility

- Enrollment
- Effective date of coverage
- Benefits
- Eligibility for benefit packages

Prior to Enrollment

Application for enrollment

- Genetic information (family history)?

Health Risk Assessment

- Genetic information (family history)?
- Prior to enrollment?

HRA for premium benefit package

- Genetic information?

Inadvertent Collection

Collect genetic information in:

- Applications for enrollment
- In providers' medical files
- Acquisition of another company

Exception for incidental collection:

- If reasonable to anticipate collection,
- Must explicitly ask not to provide

Incidental Exception

“In answering these questions, please do not include any family medical history or any information related to genetic testing, genetic services, genetic counseling, or genetic diseases.”

For Underwriting

■ Cannot collect for “underwriting”

Broad
definition:

- Computation of premium or plan contribution
- Application of pre-existing conditions
- “Other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits”
- And . . .

For Underwriting

Broad Definition (con't):

- Rules for eligibility for benefits
- Determination of eligibility for benefits

For Underwriting

**“Benefits”
include
reducing:**

- Deductible
- Premium
- Copayment, or
- Other cost-sharing mechanisms

**“Eligibility”
includes
for:**

- HRAs,
- Wellness Programs,
- Disease management programs,
- etc.

For Underwriting

Premium reduction for HRA

- Genetic information?

Disease management program

- Additional benefits?
- Genetic information?

Two HRA approach

- Genetic info, no reward
- No genetic info, with reward

Medical Appropriateness Exception

- Member seeks benefit
- May collect to determine if medically appropriate
- Minimum necessary applies

Medical Appropriateness

**Mammogram
> 40 or with
gene**

- Medically appropriate genetic test

**Diabetes DM
program**

- Medically appropriate (if necessary)
- But *not* in pre-screening

**Diabetes DM
program
(reward)**

- Exception does not apply

Individual Market

**No genetic
information
for:**

- Rules for eligibility to enroll
- Preexisting condition exclusions
- Setting premiums

Individual Market

Manifestation of disease or disorder

- May use individual's manifestation of disease or disorder
- But manifestation in one cannot be used in rating another

Individual Market

**No
collection of
genetic
information**

- Prior to enrollment
 - Incidental exception
- For underwriting
 - Medically appropriate exception

Privacy Rule & GINA

GINA Section 105

Genetic information = PHI

Prohibit use or disclosure for “underwriting”

- Group health plans
- Health insurance issuers
- Issuers of Medigap policies

Privacy Rule & GINA

OCR Proposed Rule (10/7/09)

Final Rule—tied to HITECH Act?

**Compliance Date: 6 months after
Effective Date**

Privacy Rule & GINA

Expand Scope: all health plans

- Medicare (A & B)
- Medicaid
- Long term care policy issuer
- Limited scope vision/dental

Policy Reasons

- Uniformity
- Impact of underwriting restriction

Privacy Rule & GINA

Same broad definition of “underwriting”

- Computation of premium or plan contribution
- Application of pre-existing conditions
- Other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits
- Rules for and determination of eligibility for benefits

Privacy Rule & GINA



**No genetic information
for underwriting**

**No
waiver/authorization**

No effect of providers

GINA & Privacy Notices

Privacy Practices Notice

- No genetic information for underwriting

HHS: “right to be informed”

Material change to notice

- 60 days to notify members

GINA & Privacy Notices

- **Prevent “undue burden”**
 - HITECH Act NPP changes
- **Options proposed**
 - Next annual mailing
 - Specified extension for GINA
 - HHS waiver when appropriate
 - Require notice in 60 days

QUESTIONS

Non-Discriminating Tastes Family History, GINA, and You

**Blue Cross Blue
Shield Association**

May 18-20, 2010
New Orleans, LA

Thomas D. Bixby
Law Office LLC
(608) 661-4310
TBixby@tbixbylaw.com