

# HIPAA Issue Spotting

## Blue Cross Blue Shield Association Legal Department Cooperative Teleconference

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Blue Cross Blue Shield Association is an association of independent Blue Cross and Blue Shield companies.



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## AGENDA

### HIPAA issue spotting: Specific examples--

1. Cooperation in Addressing Opioid Crisis
2. ACO or Complex Payment Arrangements
3. Drug Rebates from Pharmaceutical Manufacturers
4. Nasty Comments on Facebook
5. Unencrypted E-mails/Texts
6. Questions

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## Cooperation in Addressing Opioid Crisis

The Medical Director wants to use members' prescription drug records to identify individuals who may be victims of the opioid crisis. The Director wants to provide that information to case managers to work with those members. Moreover, the Medical Director wants to disclose this information:

- To health care providers to address potential abuse and to aid in treatment;
- To another health plan, for members who change health plans at the first of the year.

### Issue: Disclosing PHI for Opioid Crisis?

- **Office for Civil Rights concern about issue**
  - **Request for Information** (Dec. 14, 2018)
    - Ways to modify HIPAA Rules
    - Remove regulatory obstacles
    - Decrease regulatory burdens
  - **Promote care coordination/case management**
  - **“Reluctance” to disclose PHI due to HIPAA**
    - Outreach & education on current provisions sufficient?
- **Covered entities may generally exchange PHI**
  - **For Treatment, Payment, Health Care Operations**
  - **Including case management and care coordination**

## Issue: Disclosing PHI for Opioid Crisis?

### Covered Entity use/disclose PHI for own:

- Treatment activities (providers only)
- Payment activities
- Health care operations

### Health Care Operations include:

- Case management/care coordination
- Fraud & abuse detection and compliance
- Evaluating provider performance
- Population-based activities to improve health or reduce costs

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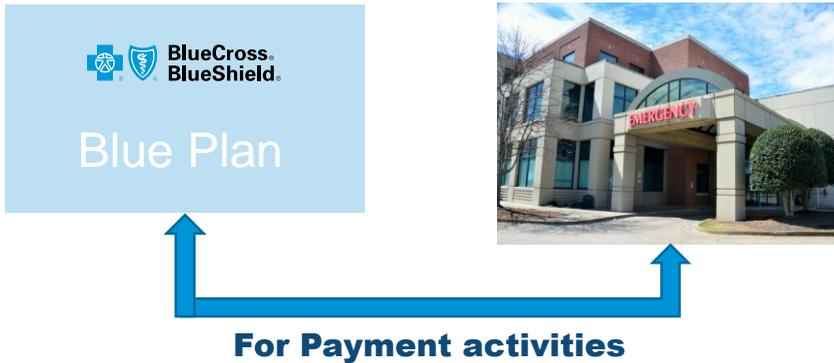
## Permitted Exchange of PHI Between Covered Entities



**For Treatment activities**

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### Permitted Exchange of PHI Between Covered Entities



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### Permitted Exchange of PHI Between Covered Entities



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## Issue: Disclosing PHI for Opioid Crisis?

### Exchanging PHI for Health Care Operations

- **Disclosure permitted if:**
  - Both covered entities have (or had) relationship with individuals;
  - The information pertains to the relationship; and
  - Disclosure is for specified health care operations
- **Specified health care operations:**
  - Health care fraud & abuse detection or compliance
  - Paragraphs (1) and (2) of HCO definition
- **Paragraph 1 includes:**
  - Case management
  - Care coordination
  - Population-based activities to improve health/reduce costs

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## Issue: Disclosing PHI for Opioid Crisis?

### Use Member Rx Information for Opioid Crisis?

- Population-based activity to improve health/reduce costs
- Blue Plan's case management/Care coordination
- Blue Plan's own health care operation

### Disclose to health care provider?

- For treatment

### Another Health Plan?

- Both plans have (or had) relationship with individuals
- Information pertains to relationship
- Disclosure is for specified health care operations

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## Issue: Disclosing PHI for Opioid Crisis?

### • Office for Civil Rights concern about issue?

- Regulatory obstacles/burdens?
- Promote care coordination/case management
- “Reluctance” to disclose PHI due to HIPAA
  - Outreach & education on current provisions sufficient?

### • Part 2 regulatory obstacles/burdens

- Consent for disclosures
- Case management /care coordination
  - Not covered by TPO consent
  - Activity conducted by providers only (*not* health plans)

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## ACO or Complex Payment Arrangement (*e.g.*, Value-Based or P4P)

A Hospital system participating in an ACO (or complex payment arrangement) with the Blue Plan wants protected health information about Blue Plan members to:

- Better understand what it will be paid under the arrangement;
- Identify diabetics and cancer patients for case management;
- Propose alternative payment arrangements; and
- Obtain reinsurance coverage, (to cover risk arrangement).

## Issue: What PHI can we disclose to Hospital?

### Understanding payment arrangement

- “Payment” = activities to obtain payment for health care
- Risk adjusting amounts due based on health status/demographics

### Identify diabetics/cancer patients

- Both covered entities have (or had) relationship with individuals
- Information pertains to relationship
- Disclosure is for paragraph (1) health care operations

### Alternative payment arrangements?

- Paragraph (5) health care operations

### Reinsurance coverage?

- Paragraph (3) health care operations

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## Issue: What PHI can we disclose to Hospital?

### Arrangements requiring special treatment

- Arrangements involving covered entities
- Clinical or operational integration among separate covered entities
- “Participants need to share protected health information . . . to manage and benefit the common enterprise”

### Organized Health Care Arrangements (OHCAs)

- Clinically integrated care setting;
- Organized system of health care;\*
- Group health plan & health insurer/HMO
- Two or more group health plans with same plan sponsor

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## Issue: What PHI can we disclose to Hospital?

### • Participants in OHCA: Free Exchange of PHI

- Treatment & payment and
- “*Any health care operations activities of the organized health care arrangement.*”

“The Department understands the need for entities participating in these joint arrangements to have shared access to information for health care operations purposes and intended the OHCA provisions to provide for such access.”

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## Issue: What PHI can we disclose to Hospital?

### Organized system of health care

- Hold out to the public as participating in joint arrangement
- Participate in joint activities

### Joint Activities

- Utilization review
- Quality assessment and improvement activities
- Payment activities if financial risk is shared

### Permitted disclosures: *Any Health Care Operation*

“a health plan and the health care providers in its network that participate as part of the same OHCA are permitted to share information for any of the activities listed in the definition of ‘health care operations.’”

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## **Issue: What PHI can we disclose to Hospital?**

- **Better understand what it will be paid?**
  - Permitted payment activity
- **Identify patients for case management?**
  - Both covered entities have (or had) relationship with individuals;
  - Information pertains to relationship
  - Case management is permitted health care operation
- **Propose alternative payment arrangements;**
  - Participants in OHCA?
  - Permitted health care operation
- **Obtain reinsurance coverage?**
  - Participants in OHCA?
  - Permitted health care operation

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# **Pharmaceutical Manufacturers' Drug Rebates**

Business personnel want to obtain rebates from Pharmaceutical Manufacturers for prescription drugs covered (and paid for) by the Blue Plan. But the manufacturers insist on getting protected health information to demonstrate that the prescriptions were actually filled (and paid for). They also insist that no business associate agreement is necessary.

## Issue: Can we disclose PHI to third party?

### TPO disclosures to third-parties

- Recipient does not have to be covered entity (or BA)
  - Law Enforcement (health care fraud)
  - Automobile insurance
  - Medical Malpractice insurance (provider)

“Whether a disclosure is allowable for health care operations . . . is determined separately from whether a business associate contract is required.

“These provisions of the rule operate independently.”

“Disclosures for health care operations may be made to an entity that is neither a covered entity nor a business associate of the covered entity.”

- Recipient does not perform a *covered function*
  - Law Enforcement (**not what health plans do!**)
  - Automobile insurance (**not what health plans do!**)
  - Medical Malpractice insurance (**not what providers do!**)

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## Issue: Can we disclose PHI to third party?

### HHS Guidance: Permitted disclosures to third-parties:

- A health plan may disclose protected health information “to a pharmaceutical manufacturer for purposes of adjudicating claims submitted under a drug rebate contract”;
- A health care provider may disclose protected health information “to obtain reimbursement from a disability insurance carrier”
- Disclosures to obtain payment under (or to underwrite) a contract for reinsurance/stop loss coverage are permitted;
- A collection agency (acting as BA) “is permitted to contact persons other than the individual . . . as necessary to obtain payment for such services.”
- A lawyer (acting as a BA) may disclose protected health information to “opposing counsel, fact witnesses, or other persons who do not perform functions or services that assist the lawyer in performing its services”

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## Issue: Can we disclose PHI to third party?

### Disclose PHI to Pharmaceutical Manufacturer for drug rebate program?

- Not a covered entity
- Not a business associate
- Not a problem!
  - Minimum protected health information necessary for health plan's payment activity

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## Social Media: Nasty Comments on Facebook

Public Relations personnel received negative comments about the Blue Plan on social media. The comments are totally unjustified and PR personnel want to know what we can do to respond.

## Issue: How can we respond on Social Media?

### Protected Health Information

- Information that relates to past, present, future:
  - Health or condition of an individual;
  - Provision of health care to an individual; or
  - Payment for the provision of health care to an individual
- Provided that the information affords a reasonable basis for identifying the individual
- Information cannot stop being PHI, unless de-identified
  - “A covered entity may determine that . . . information is not [protected health information] only if [the information has been de-identified].” 45 C.F.R. § 164.514(b).

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## Issue: How can we respond on Social Media?

### Can't Use Protected Health Information

- Including information from Member's post
  - Can't use name
  - Can't describe situation so that third party can identify Member
- Describe processes available to Members generally
  - Appeal process
  - Independent review
- Studies showing ineffectiveness of procedure/medication, etc.
- But it's pretty one-sided

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## Issue: How can we respond on Social Media?

### Alternative Structure for Covered Entities

- Hybrid Entity (parts of which are not subject to HIPAA)
  - Covered entity that performs “non-covered functions” and
  - Designates “components” that perform “covered functions”
- Covered Functions
  - Functions that make entity health plan, provider, or clearinghouse
- Health Care Components
  - Any “component” that would be covered entity or business associate
- Compliance requirements
  - Safeguards: Firewall to treat components as separate legal entities
  - Personnel may “wear two hats”
  - Policies & procedures “to ensure compliance”

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## Issue: How can we respond on Social Media?

### Hybrid Entity—Non-Health Care Component

- May respond directly to Member’s post
  - May use name and any other information Member includes in post
  - May use publicly-available information about Member/situation
  - May use information on Blue Plan’s public website
- May not use information from health care component’s records
  - Cannot review claims/appeals
  - Cannot review case management or provider notes
- Must comply with Firewall requirements
- Still not ideal, but less one-sided

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## Issue: How can we respond on Social Media?

### Other company functions—consider:

- Do we need to use protected health information?
- If access to PHI is not necessary, HYBRID ENTITY status:
  - Reduces regulatory requirements
  - Reduces administrative requirements
  - Limits regulatory risks

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## Unencrypted E-Mails (or Text Messages)

Case Management personnel want to send e-mails (or text messages) to communicate with members about their health care. If they encrypt e-mails (or text messages), Members will be less likely to participate.

## Issue: Do we have to encrypt Member E-mails?

### E-Mail contains Protected Health Information

- E-mail address (One of 18 data elements for de-identification)
- E-mail comes from Blue Plan
- E-mail likely to contain additional PHI

### E-Mail is Electronic Protected Health Information

### Security Rule applies

- 40+ Implementation Specifications (i.e., safeguards)
- “Required” vs. “Addressable” safeguards
- Encrypting transmission of PHI is “Addressable” safeguard

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## Issue: Do we have to encrypt Member E-mails?

### Addressable safeguards

- **Assess whether safeguard is reasonable and appropriate**
- **Either implement the safeguard or**
  - Document why not reasonable and appropriate; and
  - Implement equivalent alternative measure (if reasonable and appropriate)

### Flexibility of approach: specific factors:

- **Size, complexity, and capabilities of covered entity**
- **Technical infrastructure, hardware/software security capabilities**
- **Costs of security measure**
- **Probability and criticality of potential risks to ePHI**

### Costs of Security Measures

- **Costs not limited to dollars and cents**
- **Covered entity’s personnel are resources expended**
- **“Hassle factor” for members—impact on participation**

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## Issue: Do we have to encrypt Member E-mails?

- Probability and criticality of potential risks
- Intercepting e-mails—likelihood & criticality:
  - Criminal hackers
  - Family members/friends with access to account
  - Who is in best position to evaluate risk?
- HHS Guidance on “Access” requests:
  - CE “must provide a brief warning to the individual that there is some level of risk that the individual’s PHI could be read or otherwise accessed by a third party while in transit, and confirm that the individual still wants to receive her PHI by unencrypted e-mail.”
  - Note—*individual’s* request, not Plan’s request
- Criticality of potential risks
  - CE can control criticality by limiting content of e-mail

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## Issue: Do we have to encrypt Member E-mails?

### Need to make the case—Document:

- Costs of encryption (lack of participation)
- Probability and criticality of potential risks
- Member agreement to non-encrypted e-mails
- Conclusion—circumstances & content limitations

### Text Messages

- Same considerations, *plus*
- Telephone Consumer Protection Act consent

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**Questions?**