

Legal Limits On Pharmacy Adherence And Discount Programs

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Agenda

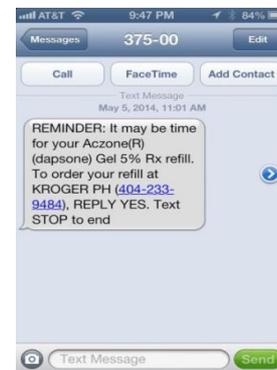
- **Overview Of Adherence & Discount Programs**
- **Privacy Standards**
- **Telemarketing Rules And Litigation**
- **Impact On U&C Reimbursement**
- **Kickbacks And Beneficiary Inducements**
 - Good news! OIG rules implement exceptions

Adherence And Discount Programs

Adherence / Compliance Programs

- **Refill Reminders**
 - Call, voicemail, text, email, apps
- **Other Adherence Programs**
 - Notice to pick up Rx
 - Take as prescribed (e.g., full course of antibiotics)
 - During MTM or Medicare comprehensive med review
- **Adherence Programs Work**
 - Non-adherence is a \$290 Billion a year problem
 - Adherence programs increase patient health and decrease overall healthcare costs

WE BROUGHT ONE-TOUCH REFILL REMINDERS TO APPLE WATCH



Discounts, Coupons, Rewards Programs

- **Pharmacy Programs**
 - Coupons, copay waivers, loyalty programs
- **Plan Programs**
 - Preferred pharmacy copays, copay waivers
- **Manufacturer Programs**
 - Copay coupons, PAPs
- **Rx Discount Cards**



Privacy Standards

HIPAA Privacy Issues

- **General Rule**
 - Pharmacy may use protected health information (PHI) for treatment, payment and healthcare operations
- **Marketing**
 - Communication that encourages “purchase or use” of product or service
 - Patient authorization required if use PHI for marketing
- **Are Adherence Programs “Treatment” Or “Marketing”?**
 - Should the answer change if a pharmacy earns \$ doing it?

NON-Subsidized Adherence Programs

- **HIPAA HITECH Definition Of “Marketing”**
 - Exemption for communications “about a drug or biologic that is currently being prescribed for the individual...”
- **Exemption Includes:**
 - “Refill reminders”
 - “Adherence communications encouraging individuals to take Rx as directed”
 - Communications about Rx that lapsed in past 90 days
 - Information on generic equivalents of prescribed drug
 - How to take self-administered drugs

NON-Subsidized Adherence Programs

- **Patient Authorization Required:**
 - “Communications about specific new formulations of a currently prescribed medicine”
 - “Communications about specific adjunctive drugs related to the currently prescribed medicine”
 - “Communications encouraging an individual to switch from a prescribed medicine to an alternative medicine”
 - But OCR suggests “may” allow similar communications if truly “treatment” and no payment received
- **Other Major Exemption**
 - Authorization not normally required for “face-to-face” adherence communications

SUBSIDIZED Adherence Programs

What If Manufacturer Pays For Refill Reminders Concerning Its Drug?

- Statute: Patient authorization not required if “financial remuneration” to pharmacy is “reasonable in amount”
- Rule: Patient authorization not required if “financial remuneration” is “reasonably related” to pharmacy’s “cost of making the communication”
- OCR Guidance: Payment to pharmacy “may cover only the reasonable direct and indirect costs ... including labor, materials, and supplies, as well as capital and overhead costs”
- Pharmacy profit allowed only if patient signs authorization

SUBSIDIZED Adherence Programs

- **Business Associate May Operate Program**
 - BA may be paid for “the fair market value of the business associate’s services”
 - So BA may earn a profit without patient authorization
- **HIPAA Allows Other Payments To Pharmacies**
 - Manufacturer may fund government mandated communications
 - REMS
 - Only “financial remuneration” is restricted
 - Payment with services, supplies, etc. not restricted
 - Payments by health plans allowed
 - Limits apply to payments by manufacturer of product involved in communication

Discounts And Rewards Programs

- **Privacy Concerns Depend On Specific Use (Or Abuse) Of Protected Health Information**
 - Use front end purchase info to earn Rx discounts
 - Not PHI so no HIPAA problem?
 - Use Rx purchase info to earn Rx or non-Rx discounts
 - Is PHI involved if only track the fact that a patient filled an unidentified Rx? What if Rx dollar amount is tracked too?
 - Using specific Rx info to earn discounts on related front end items may be problematic
- **Patient Authorization**
 - Pharmacies can limit problems by obtaining signed HIPAA authorization when patient enrolls in discount/loyalty program

Telemarketing Rules And Litigation

The image displays three overlapping screenshots of the Law360 website, each showing a news article related to telemarketing litigation. The top article is titled "Walgreen To Pay \$11M To End Prescription Robocall Suit" by Caroline Simson, dated March 27, 2014. The middle article is titled "CVS Hit With TCPA Suit Over Unsolicited Text Messages" by Lisa Ryan. The bottom article is titled "Rite Aid Customer Seeks Class Cert. In Telemarketing Suit" by Jonathan Randles, dated December 23, 2014. The Law360 logo and navigation elements are visible at the top of each screenshot. The bottom right corner of the image features the Wyrick Robbins logo, consisting of the letters "Wr" in a grey square above the text "wyrickrobbins".

LAW360 News, cases, companies, firms Advanced Search

Walgreen To Pay \$11M To End Prescription Robocall Suit

By Caroline Simson

Law360, New York (March 27, 2014) -- Walgreen Co. has agreed to pay \$11 million to end a class suit accusing it of making unsolicited robocalls to customers' cellphones.

LAW360 News, cases, companies, firms Advanced Search

CVS Hit With TCPA Suit Over Unsolicited Text Messages

By Lisa Ryan

CVS Health Inc. was slapped on Tuesday with a lawsuit accusing the drugstore chain of making unsolicited text messages to consumers in violation of the Telephone Consumer Protection Act.

LAW360 News, cases, companies, firms Advanced Search

Rite Aid Customer Seeks Class Cert. In Telemarketing Suit

By Jonathan Randles

Law360, New York (December 23, 2014, 5:43 PM ET) -- A Rite Aid Corp. customer suing the pharmacy in New York for making unsolicited phone calls to customers moved Monday for class certification, saying the company used the same technology to deliver nearly identical messages to thousands of consumers across the country.

Wr
wyrickrobbins

TCPA

- **Telephone Consumer Protection Act (1991)**
 - Limits autodialed or prerecorded calls and texts to cell phones without prior consent
 - Advertising or telemarketing on cells requires written consent
 - Limits prerecorded telemarketing calls to residential phones without prior consent
- **Rampant Class Action Litigation**
 - Lawsuits increased 560% in 5 years
 - Penalties of up to \$1,500 per call or text
 - Pharmacies are targets



FCC Ruling: Consent

- **Express Consent**
 - Family member can give consent if “incapacitated”
 - Consent ends when incapacity ends
 - May revoke consent by “any reasonable means”
 - Liability for using “reassigned numbers”
- **Giving Phone Number To Provider = Consent For Healthcare Messages**
 - Limited to HIPAA “healthcare” issues
 - Messages must be “within the scope of consent given”
 - “closely related” to reason patient gave out phone number

FCC Ruling: Beyond Consent

Calls & Texts Beyond Scope Of Consent Allowed If:

- Certain HIPAA “healthcare” calls or texts to number provided by patient
 - Such as “prescription notifications” and “healthcare instructions”
 - But not marketing, advertising or billing messages
- Made By HIPAA covered entity or business associate
 - Must identify provider name and contact info
- Recipient must not be charged for calls or texts
 - Even for cell plan minutes or data limits
 - Some pharmacies have agreements with major carriers
- Limited Amount
 - 1 minute or less for calls; 160 characters or less for texts
 - 1 message per day; 3 per week
- Offer “easy” opt-out, and honor opt-out requests “immediately”



Federal Trade Commission Rules

- **FTC Telemarketing Sales Rule**
 - Prohibits prerecorded “telemarketing” calls “to induce the purchase of goods or services”
- **Written Consent Exception**
- **Exception For “Purely Informational” Calls**
 - “notification of order status” and recalls, but not “mixed messages”
- **Exception For HIPAA “Healthcare Messages”**
 - “Prescription refill reminders”
 - Reminders of “availability of flu shots”
 - Calls to describe a covered health product or service
 - But not unprescribed vitamins, weight loss products, alternative therapies

CAN-SPAM Act

- **Regulates “Commercial” Emails**
 - Identify as advertisement
 - Opt-out method required – fulfill w/in 10 days
 - No false, misleading or deceptive subject or header
 - Include location
- **“Transactional” Emails Exempt**
 - “Primary purpose” test
- **Major Penalties**
 - \$16,000 per email + jail



Usual & Customary Reimbursement



U&C Reimbursement

- **CMS Medicaid Standard**
 - Pharmacy’s “usual and customary charges to the general public”
- **State Medicaid Standards Vary**
 - Cash paying customers
 - Some specifically include discount programs
 - “Most favored nation” standards
- **PBM Contract Definitions Vary**
 - Audit and recoupment issues
- **False Claims Liability**
 - Big settlements and qui tam cases



Discount Programs Can Reduce U&C

- **\$4 Generics For Everyone**
- **Loyalty And Rewards Programs**
 - Open to everyone, or limited population?
 - How limited?
 - What if pharmacy charges a membership fee?
 - Recent litigation suggests discounted price may be U&C
 - If U&C, account for membership fee?
- **Apply To Manufacturer or 3rd Party Coupons?**

Automatic Refill Programs

- **Some Medicaid Programs Prohibit**
 - Require affirmative patient authorization for refills
 - Rationale: Increased costs for unneeded Rx
 - But pharmacy not paid if Rx not picked up
 - And physician prescribed so decided medically necessary
- **Example: Massachusetts Medicaid Rule**
 - No payment for refills w/o “explicit request” by patient
 - Pharmacies accused of using auto-refill program for Medicaid patients settled for \$ millions
- **Also Medicare Limits On Mail Order Refills**

Kickbacks And Beneficiary Inducements

Anti-Kickback Statute (AKS)

- **Unlawful To:**
 1. “Knowingly and willfully”
 2. Offer, pay, solicit or receive
 3. Any “remuneration” (“kickback, bribe or rebate”)
 4. In return for purchasing or ordering an item or service (or referring patient to provider to furnish an item or service)
 5. Covered by government healthcare programs
- **Safe Harbors Discussed Later**

Civil Monetary Penalties (CMP) Law

- **Fines Imposed On Any Person Who:**
 1. Offers or transfers “remuneration” to patient
 2. That the person “knows or should know”
 3. Is likely to induce the patient
 4. To order or receive items or services covered by a government healthcare program
 5. From “a particular provider, practitioner or supplier”
- **Exceptions Discussed Soon**

Coupons And Discount Programs

- **Common Response To AKS And CMP Law**
 - Many pharmacies “carve out” government program beneficiaries from drug coupons and discount programs
 - See the fine print on coupons and in discount program brochures and enrollment forms
- **Challenge: Enforcing The Fine Print**
 - Pharmacies have been penalized for allegedly...
 - Allowing government beneficiaries to use drug coupons
 - Enrolling government beneficiaries in drug discount programs

“Nominal Value” Exception

- **OIG Advisory Bulletin (2002) & Policy Statement (2016)**
 - Allows “inexpensive gifts” of “nominal value” to government program beneficiaries
 - “retail value of no more than \$15 per item or \$75 in the aggregate per patient on an annual basis”
- **Challenge: Tracking \$75 Annual Limit**
 - Pharmacies have been penalized
 - Many pharmacies still carve out
- **CMP Exception**
 - OIG did not expressly address applicability to AKS

CMP “Retailer” Exception

1. A “retailer” ...
2. May offer “coupons, rebates, or other rewards” ...
3. To government program beneficiaries...
4. If offered on “equal terms” to the “general public” regardless of health insurance status... and
5. Not “tied” to the provision of other covered items or services

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*Tony Carilli RPH
Pharmacist/Owner*

Examples Of CMP Retailer Exception

- **Protected**
 - Supermarket gasoline discount programs
 - OIG advisory opinions 12-05 & 12-14 (2012)
 - Also no AKS liability
 - Coupon for \$20 off “anything in store”
- **Not Protected**
 - Rewards focused on covered healthcare
 - Coupon for \$20 off Rx copay
 - Coupons to transfer Rxs
 - Free test strips if patient fills insulin Rx



“Financial Need” Exceptions

- **AKS Safe Harbor & Older CMP Exception**

Pharmacy can waive or reduce copays for gov’t beneficiaries if:

1. Not advertised,
2. Not “routinely” waived, and
3. “Good faith” determination of “financial need” (or “reasonable” collection efforts fail)

[Note: 2 & 3 do not apply to patients eligible for ACA subsidies]

- **New CMP Law Exception**

Pharmacy can offer items for free or less than FMV to gov’t beneficiaries if:

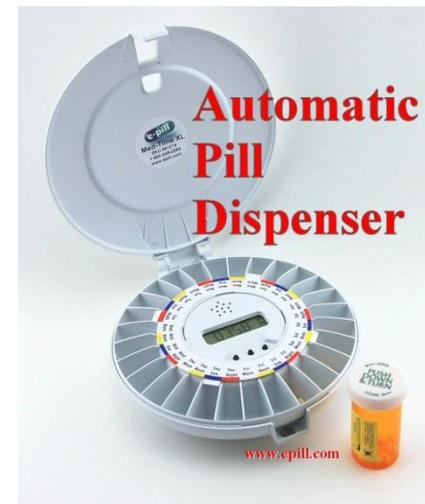
1. Not advertised,
2. Not “tied” to other covered items or services,
3. “Reasonable connection” to medical care, and
4. “Good faith” determination of “financial need”

- **Concerns**

- Unconstitutional advertising restrictions?
- What is “routine” and “reasonable”?
- Unworkable requirements for determining financial need?

CMP “Access To Care” Exception

- **“Remuneration” Does Not Include Items Or Services That:**
 1. Improve patient’s “ability to obtain items and services” covered by Medicare or Medicaid, and
 2. “Pose a low risk of harm” because unlikely to:
 - a) Interfere with clinical decisions
 - b) Increase costs to government or patients, or
 - c) Raise patient safety or quality of care concerns
- **Must Enable Access, Not Reward Utilization**
 - Not OK: Movie tickets or \$20 debit card for each patient
 - OK: “item that dispenses medications at a certain time”
 - OK: “subscription to a web-based food and activity tracker”
 - OK: informational or educational programs
 - OK?: refill reminder devices or programs



CMP “Preventive Care” Exception

- **CMP Law**
 - Allows “incentives ... to promote the delivery of preventive care”
- **“Preventive Care”**
 - Defined By U.S. Preventive Services Task Force
 - Includes many screenings like blood pressure, immunizations, vitamins, tobacco cessation, etc.
- **Rule Says Incentives...**
 - Can’t be “tied” to provision of other covered services
 - Can’t be cash or “convertible to cash” (e.g., debit card)
 - Can’t be “disproportionately large”



Drug Plan Exceptions

- **“Preferred” Pharmacies (Medicare Modernization Act)**
 - Medicare drug plans charge lower copays at certain pharmacies
 - Based on PBM-pharmacy contracts
- **Generic Drugs**
 - Medicare plans may waive copays for “first fill” of a generic drug
 - Plans decide, not pharmacies
- **Drug Cost Differentials**
 - AKS and CMP exceptions for certain differentials in copays and deductibles as part of benefit plan design
 - Plans decide, not pharmacies

Drug Manufacturer Exceptions

- **Medicare “Donut Hole” Discounts**
 - Discounts allowed for patients in Medicare Coverage Gap Discount Program
 - AKS Safe Harbor & CMP Exception
- **Assistance Programs**
 - OIG allows manufacturer donations to “independent charities”
 - “provide financial support to patients without regard for the particular medication a patient may be using”

Manufacturer Copay Coupons

- **OIG Report & Special Advisory Bulletin (2014)**
 - May be kickbacks to get patients to use manufacturer's drugs
 - Notices and pharmacy claims procedures may be insufficient to ensure Medicare patients don't use
 - “pharmacies that accept manufacturer coupons for copayments owed by Federal health care program beneficiaries ... may be subject to sanctions under the anti-kickback statute”
 - OIG recognized financial and adherence benefits to patients ... but suggested donating to charities instead

Adherence As Kickback

- **Sponsored Pharmacy Programs**
 - Lawsuits challenge alleged kickbacks by manufacturers for drug adherence programs
 - Can try to satisfy “personal services” safe harbor
 - Manufacturer pays “fair market value” for refill reminders or education
 - Payments not tied to drug switching or utilization
 - Still face HIPAA and other limits
- **Offered “Adherence Safe Harbor” To OIG**
 - Would protect sponsored adherence programs IF
 - no incentive for switching or extending Rx
 - Patient eligibility not based on potential referrals for sponsor
 - Sponsorship disclosed to patients and other requirements

Conclusion

- **Adherence And Discount Programs Are Good**
 - Save money and save lives
- **But Face Complex Web Of Legal Limits**
 - Privacy standards
 - Telemarketing rules
 - Reimbursement limits
 - Anti-kickback statute (with safe harbors)
 - Civil monetary penalties law (with exceptions)
- **Be Careful!**
 - “No good deed goes unpunished”

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