Health Information Technology
and
Patient Health Engagement

Technology with a fifteen-year track record of supporting secure, high quality, effective and affordable healthcare is now at risk

"The spread of health IT holds tremendous promise for improving patient care, reducing medical errors and lowering costs. . . . With the right safeguards in place, consumers will be able to trust health IT systems and doctors and providers will be able to confidently use this infrastructure to improve patient care."

Statement of then Rep. Edward J. Markey, a senior member of the House Energy and Commerce Committee, Feb. 14, 2008, http://www.markey.senate.gov/news/press-releases/feb-15-2008-markey-emanuel-intro-bill-to-promote-health-it-while-protecting-patient-privacy

"Widespread use of health IT within the health care industry will improve the quality of health care, prevent medical errors, reduce health care costs, increase administrative efficiencies, decrease paperwork, and expand access to affordable health care. It is imperative that the privacy and security of electronic health information be ensured as this information is maintained and transmitted electronically."

U.S. Dept. of Health and Human Services,("HHS") http://www.hhs.gov/hipaa/for-professionals/special-topics/health-information-technology/index.html

Patient Health Engagement (PHE)

- **Definition and Background**
  - PHE is the use of multi-channel communications to involve/activate individuals in specific aspects of their health
  - PHE integrates with clinical and administrative systems at Covered Entities, and uses PHI to trigger personalized communications tied to specific events (e.g., gaps in care, in-home monitoring, EOB, Medicaid recertification)
  - PHE uses automated communications (calls, SMS, email) to triage large populations, so other resources can focus on those who need the most help
  - In existence since 2000, PHE has a strong, verified track record of positive health outcomes and patient/user experiences and acceptance

CFAH CENTER FOR ADVANCING HEALTH

Evidence. Engagement. Equity.

"Health engagement supports people in taking care of themselves, whether that's getting a flu shot, having their screenings, filling their prescriptions, etc. These health behaviors have proven to dramatically reduce long-term care costs. Ultimately, better health feels good, costs less, and increases productivity—a win for all."

Gruman J, Holmes-Rovner M, French ME, Jeress D, Sofaer S, Shaller D, Prager DC. From patient education to patient engagement: Implications for the field of patient education. Patient Education and Counseling. March 2010 (Vol. 78, Issue 3, Pages 350-356, DOI: 10.1016/j.pec.2010.02.002) Full Report (p. 144)

Some numbers for just three diseases….

Diabetes:

- 21 million diagnosed
- 8 million undiagnosed
- 71,000 deaths annually
- 86 million with pre-diabetes
- $245 billion

(http://www.cdc.gov/diabetes/data/statistics/2014statisticsreport.html)

High Blood Pressure/Coronary Artery Disease

- 70 million diagnosed
- Less than 52% with BP under control
- $46 billion

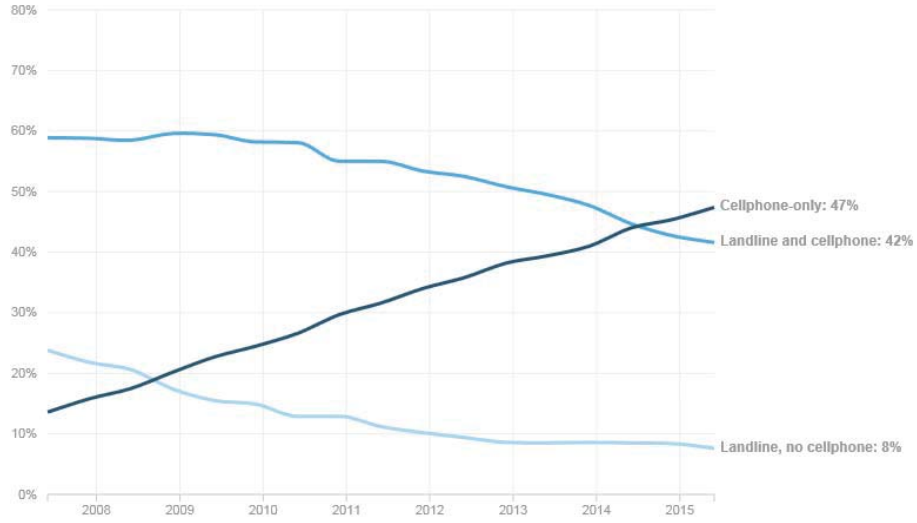
(http://www.cdc.gov/bloodpressure/faqs.htm)

Colon Cancer

- 135K annual diagnoses annually
- 52K fatalities, #2 cancer killer in US, screening rates at <50% of EBM recommendations
- $14 billion

(http://www.cdc.gov/cancer/colorectal/statistics)

CDC Study



Characteristics of Wireless-Only Households:

- Lower income
- Single head-of-household
- Less likely to have health insurance
- Less likely to have a primary care physician
- More likely to have one or more gaps in recommended health screenings
- More likely to engaged in risky health behaviors

"What we started to recognize, however, fairly quickly, is that, in fact, their health characteristics were different, even when you controlled for all of those demographic differences. People who are wireless-only are more likely to smoke, they're more likely to binge drink, they're more likely to be uninsured. In effect, they are more likely to engage in risky behaviors."

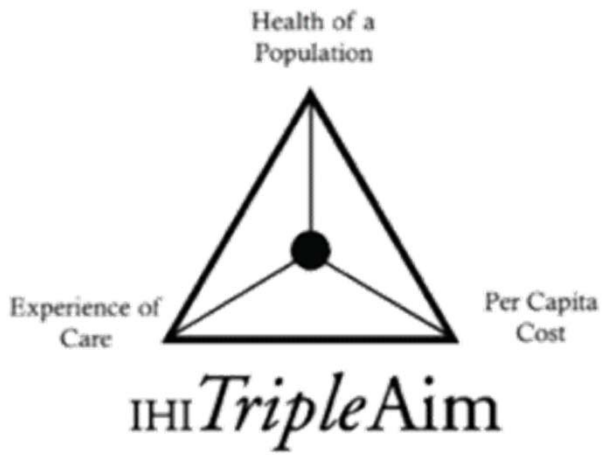
Stephen Blumberg, Associate Director for Science in the division of Health Interview Statistics at the CDC's National Center for Health Statistics (http://www.npr.org/sections/alltechconsidered/2015/12/03/458225197)

- Full study results: http://www.cdc.gov/nchs/data/nhis/earlyrelease/wireless201512.pdf

Health Outcome Example

PHE provider reached out to over 400K Medicare beneficiaries with information about colorectal cancer screening. The outreach assessed and addressed planned behaviors around screenings. A 90-day post analysis based on claims data indicated:

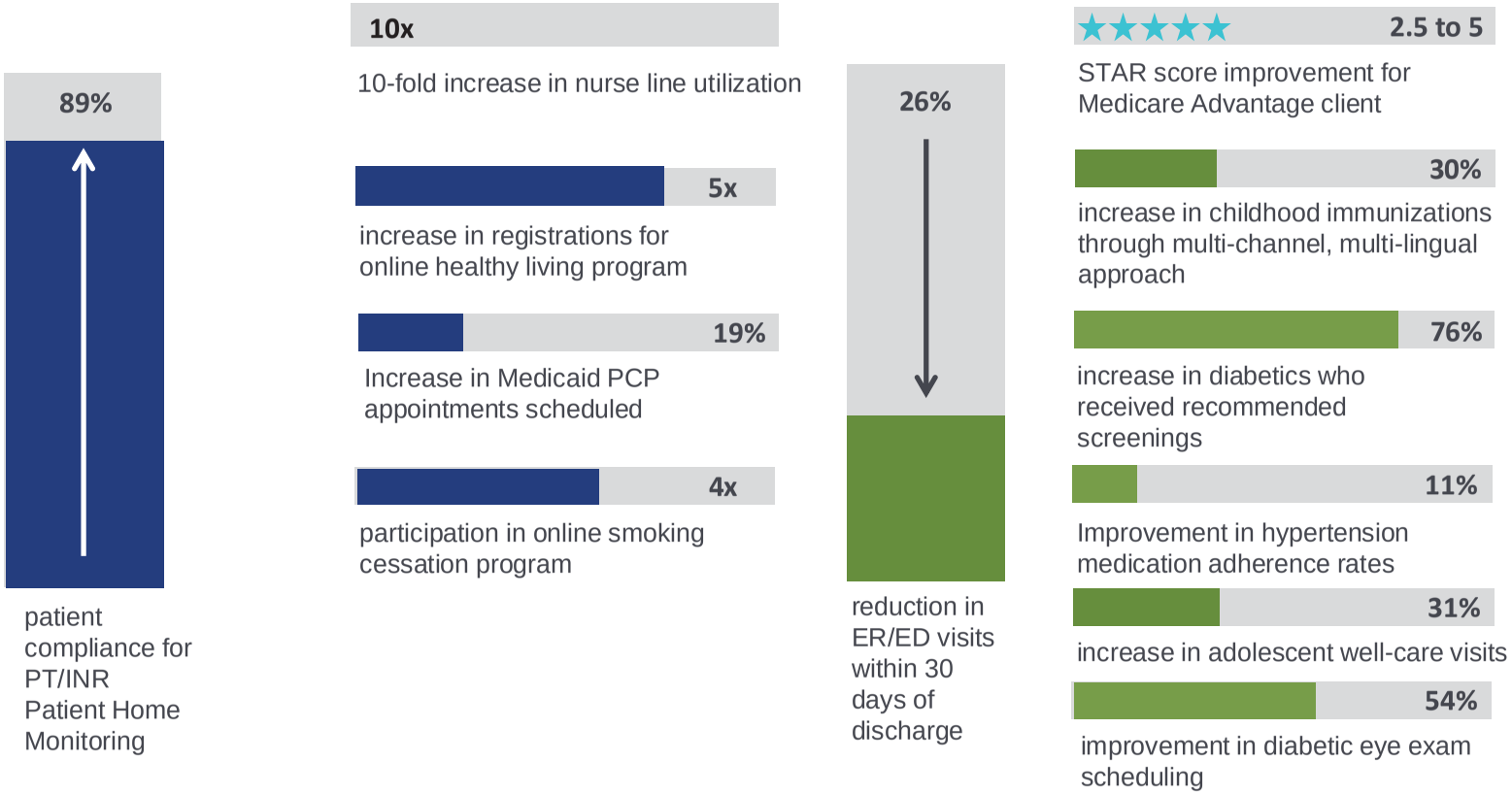
- *Experience of Care:*
  299 cases of colorectal cancer were identified through the outreach
- *Health of Population:*
  about half of these cases were in a stage of early detection
- *Per Capita Cost:*
  Proposed savings of about $24,000 – $34,000 per early cancer stage detected



Source: IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2012.

Source: client data

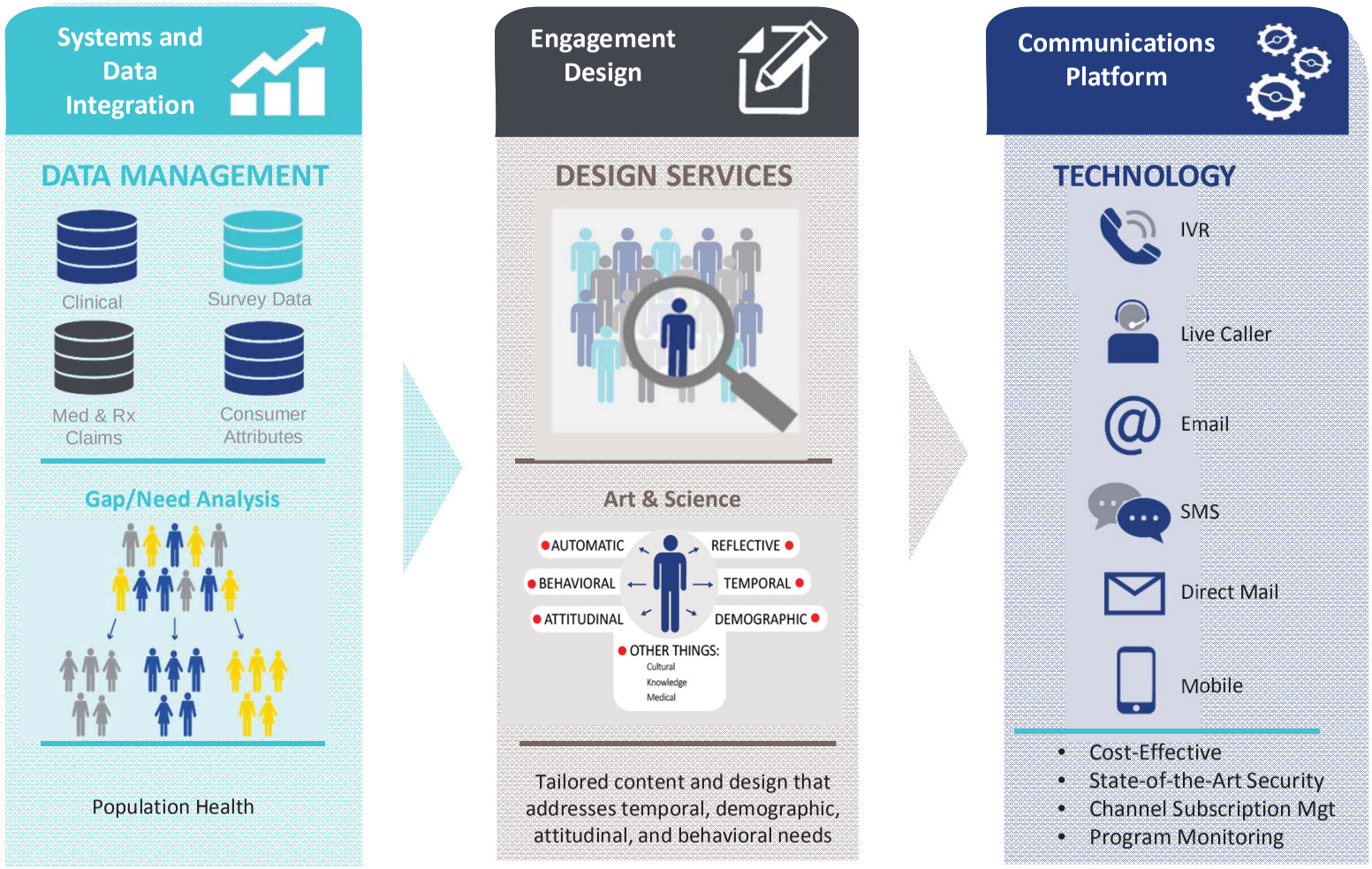
More Health Outcome Examples



Source: client data

PHE - How It Works

Triple Aim Goal: Improve Care Experiences, Advance Population Health, Reduce Costs



Compliance, Regulatory, and Security Requirements

- **PHE is subject to extensive federal (i.e., HIPAA) and state statutes/regulations that govern privacy, security, and communications, since PHI is used/generated by both Covered Entities and their Business Associates**
  - Each Business Associate's compliance team is lead by a required internal Privacy and Security Officer, with support from legal counsel
  - These teams report to executive committees that must formally review plans, status, issues, and resolutions
  - Business Associates are required to develop, document, and test Information Security Management Systems (physical, technical, and administrative safeguards)
    - E.G., secure data enters, 256-bit AES encryption on all data in transit and at rest, employee background checks and training programs….

Compliance, Regulatory, and Security Requirements

- **Additional Requirements under HIPAA and state statutes/regulations:**
  - Audits/certifications are required of all Business Associates, by independent, certified bodies (e.g., ISO-27001, NIST, HITRUST)
  - Annual audits of Business Associates by ISO, each Covered Entity, contractual requirements for HHS to access all applicable books and records upon request
  - Prior review/approval of program design and content by the Covered Entity
  - And prior review/approval by CMS or State Medicaid for any government-funded populations

Covered Entities and Business Associates Under HIPAA

Do's

- Technical, physical, and administrative safeguards
- Documented privacy/security policies
- Encryption, user authentication, security badges and cameras,
- Employee background checks and training
- Internal and external audits and approvals
- Minimum necessary standard for use of PHI
- Informational content about gaps in care, existing benefits

Don'ts

- Unsecured PHI in any format
- Random or blast calling
- Conducted by untrained staff
- Sale or disclosure of PHI
- Contacts, content or program design that has not been pre-approved
- Communications about selling or marketing anything

PHE - Truths & Myths

What it is

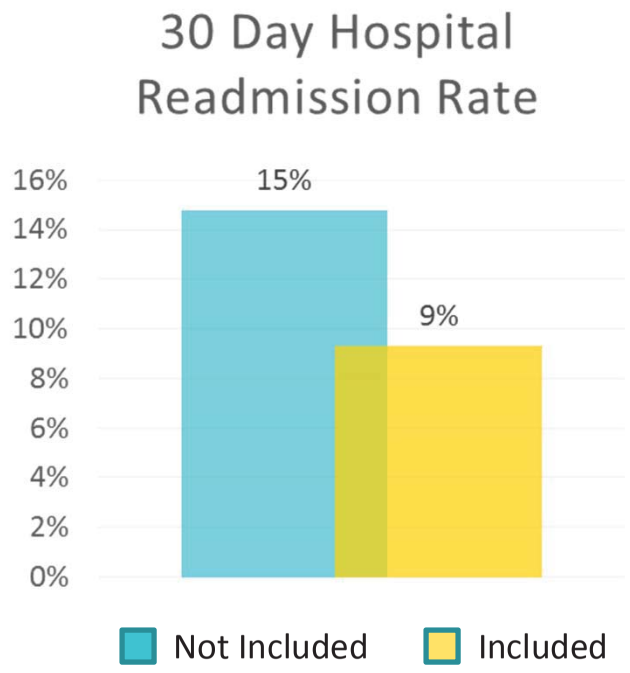
- Multi-channel (IVR, SMS, E-Mail, regular mail, and Live Nurse/Admin)
- Interactive and personalized
- Targeted, scheduled, intelligent
- Triggered from a system/need (<3 times per year, per patient, on average)
- Respectful and well-intentioned
- Extensively regulated
- Conducted only by Covered Entities and Business Associates with relationship with patient/member
- Subject to extensive independent security and quality reviews

What it isn't

- Not IVR/calling Only
- Not typical "Robocalls"
- Not blast or random calling
- Not easy or inexpensive to do
- Not marketing or selling
- Not spamming or incented to over-communicate
- Not conducted by numerous or unqualified organizations
- Not tolerant of poor user experiences. These are existing members/patients!

Patients Included in PHE Programs Have Better Clinical Outcomes Than Patients Not Included

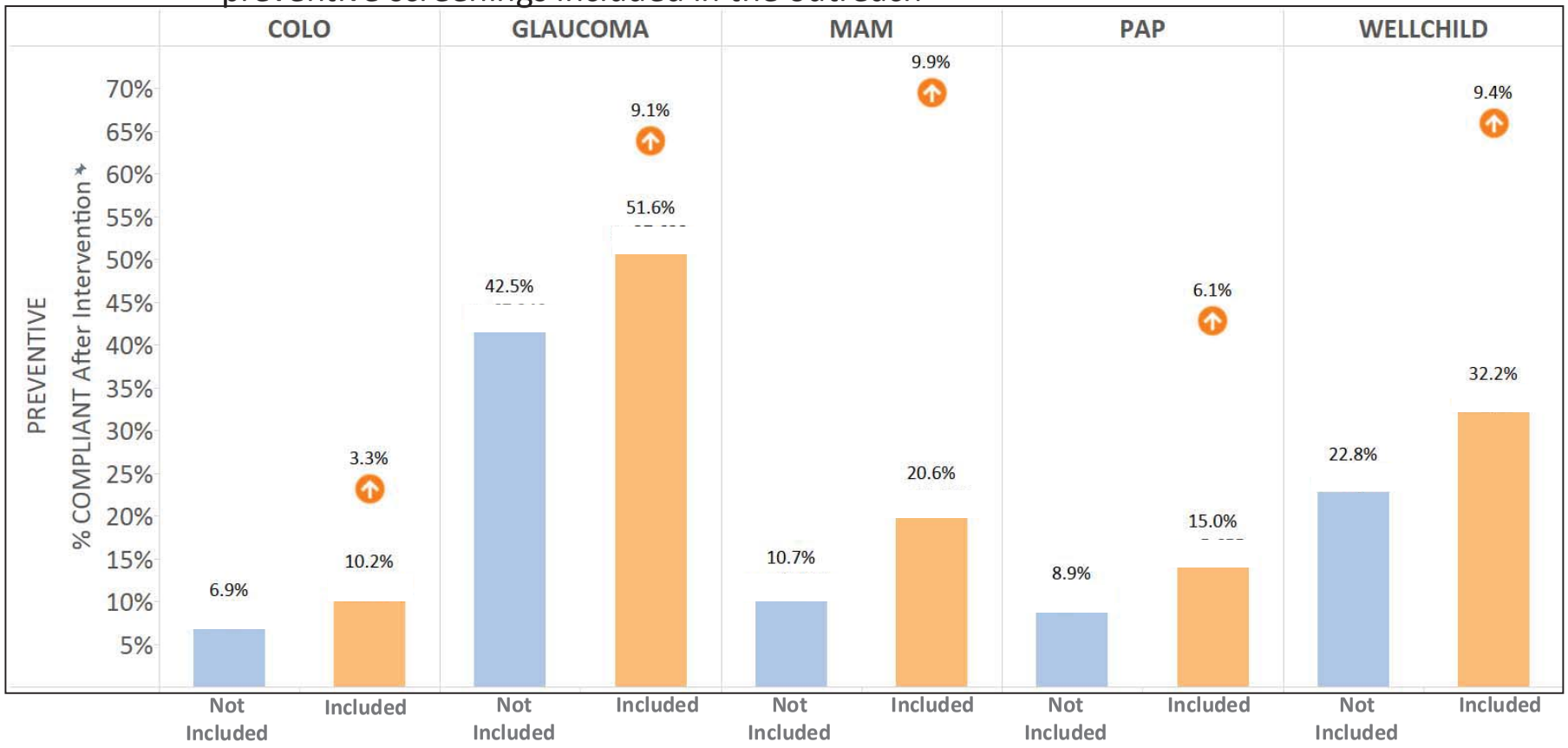
- *POST HOSPITAL DISCHARGE SUPPORT* PROGRAMS Provide:
  - TRIAGE: 10-20% of patients included in these programs need intervention from a nurse or case manager, and are transferred in real time for immediate support
  - CLINICAL OUTCOMES: Patients receiving post-hospital discharge support are less likely to be readmitted to the hospital than those who are not included in the program



Outcomes based on client provided hospital readmission data through May 2015

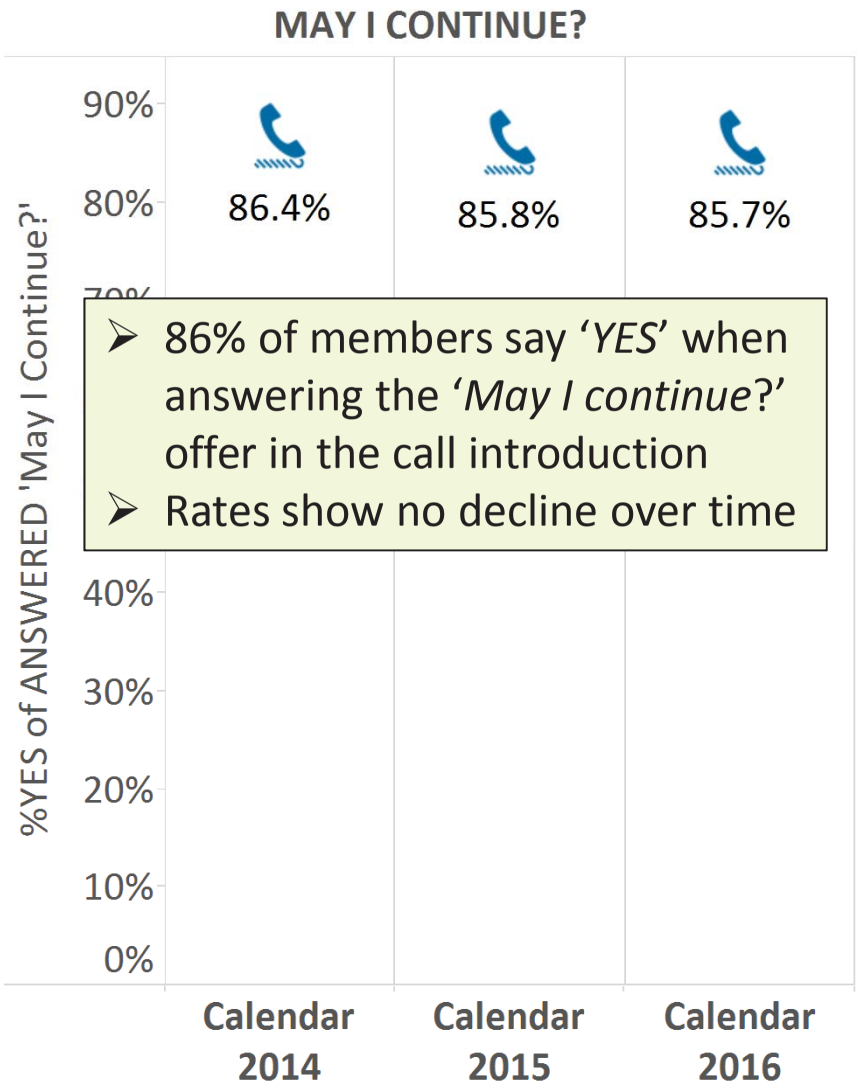
Encouraging Good Health: Patients with a History of Non-Compliance Have Higher Gap Closure Rates with PHE

- *Preventive Screening Reminder* programs provide information and support about screenings to patients who are non-compliant with those screenings
  - Intervention groups have increased rates of preventive screening compliance for all preventive screenings included in the outreach

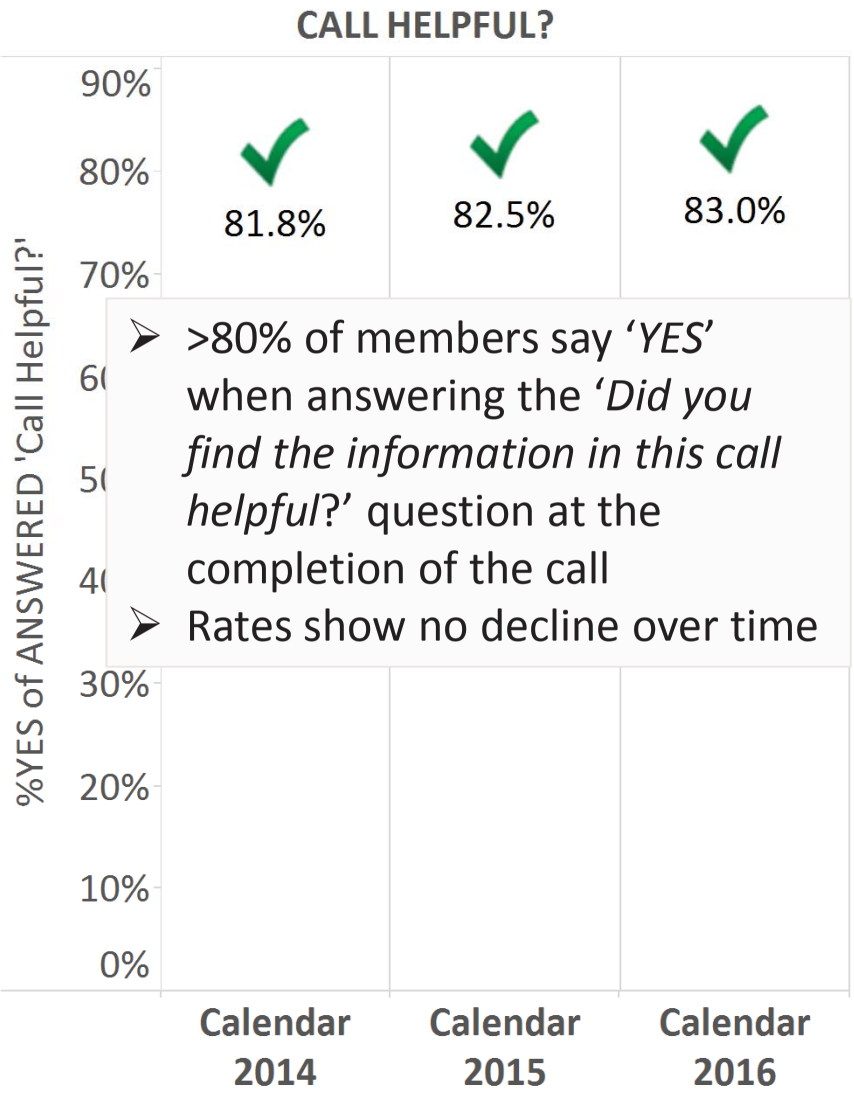


All patients in both cohorts were non-compliant with the screening at the time of the intervention. Rate shows the % of total patients in each group who were compliant 3 months after the intervention was completed.

Key Performance Metrics Track Permission to Proceed (at call initiation) and Satisfaction with Content (at call completion)



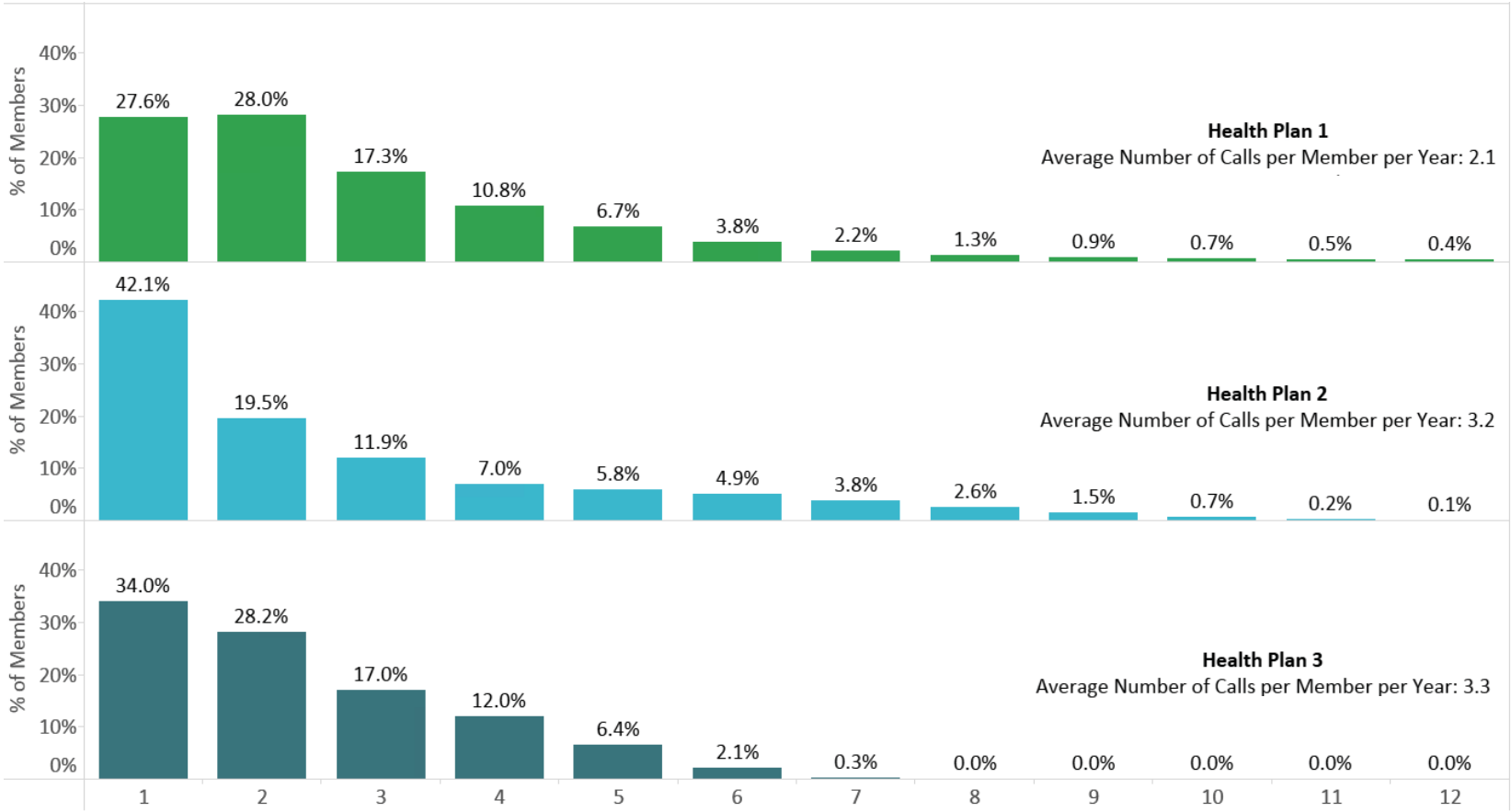
- 86% of members say '*YES*' when answering the '*May I continue*?' offer in the call introduction
- Rates show no decline over time



- >80% of members say '*YES*' when answering the '*Did you find the information in this call helpful*?' question at the completion of the call
- Rates show no decline over time

Health Plans Have No Incentive to Over-Contact Their Members/Patients

- Calls/texts are placed based on flags from clinical and administrative systems based on gaps/need
- Contact frequency aligns with patient status – sicker patients are called more often (e.g., in-home support of chronically ill) than healthier patients
- The data includes all calls across many program types for three different national health plans



Data represent all outbound phone calls from January 1, 2015 through December 31, 2015 for three different national health plans

Recognition – PHE's Positive Impact

In short . . .

PHE works to lower costs, engage patients and improve their overall health care!

Background Information

- **PHE providers are Business Associates to Covered Entities defined under HIPAA and HHS's HIPAA Privacy Rule.**
  - Covered Entities are:
    - — Health care providers
    - — Health plans
    - — Health care clearinghouses
- **Covered Entities and Business Associates are each part of HIPAA's complex and comprehensive regulatory scheme**
  - Each are subject to HIPAA and the same rigorous privacy and data security regulations under the HIPAA Privacy Rule
- **HIPAA Privacy Rule allows <u>all</u> communications using PHI, <u>without</u> patient/member's authorization related to:**
  - Treatment, Payment, <u>and</u> Health Care Operations 45 C.F.R. § 164.506

Background Information

"Ready access to treatment and efficient payment for health care, both of which require use and disclosure of protected health information, are essential to the effective operation of the health care system. In addition, certain health care operations – such as administrative, financial, legal, and quality improvement activities – conducted by or for health care providers and health plans, are essential to support treatment and payment."

HHS OCR HIPAA Privacy, "Uses and Disclosures for Treatment, Payment, and Health Care Operations," Dec. 3, 2002, rev. April 3, 2003

The Telephone Consumer Protection Act Issue

- **Certain Covered Entities and their Business Associates are not treated equally by the FCC, with inconsistencies between the FCC's 2015 Declaratory Order, 2012 Report & Order, FTC's Telemarketing Sale Rule ("TSR") 2008 Amendments, HIPAA and HHS's HIPAA Privacy Rule**
  - FTC's TSR HIPAA-related 2008 Amendment applies to all Covered Entities and their Business Associates and any health care message
  - FCC's 2012 Robocall Order HIPAA exemption applies to all Covered Entities and their Business Associates and any health care message
  - FCC's 2015 Declaratory Order could be misinterpreted to only apply to "health care providers" – excluding two other important classes of Covered Entities – health plans and health care clearinghouses
    - Also limits scope of "health care" messages expressly allowed under HIPAA

Value and Importance of Health Plans

- **Health plans are a very important part of a complex, integrated and comprehensive health system and are essential to its effective operations**
  - HIPAA Privacy Rule governs all health-care related messages, not just messages from healthcare providers
- **Health plans are responsible for much more than administrative functions**
  - Population health, clinical quality, gaps in care (e.g., HEDIS and Medicare STARS)
  - Health plans have Medical Directors, large clinical quality groups, nurses, care and disease management programs, etc.
  - Under ACA, health plans increasingly collaborate with healthcare providers to manage population health and clinical risk
- **Examples of exigent, heath-related communications provided by health plans**
  - Pre-operative instructions and post-discharge follow-up
  - Disease management and in-home patient monitoring to improve health outcomes
  - Prescription refill reminders and drug-recall notifications
  - Preventative screenings for diabetes, cancer, and other diseases
- **Therefore, messages re: coverage, benefit changes, pre-authorization, billing, and payment can be critical to the expedient and efficient delivery of health care treatments**

HIPAA Privacy Rule

- **HIPAA Privacy Rule distinguishes "marketing" messages from those about goods and services that "are essential to quality health care"** HHS OCR Privacy, "Marketing, "Dec. 3, 2003, rev. April 3, 2003
    - Patient's prior authorization is required for marketing messages - 45 C.F.R. § 164. 508(3).
    - Messages regarding Covered Entities' own products/services, **treatment, case management or care** are not marketing - 45 C.F.R. § 164.506(c)
    - Covered Entities and Business Associates may use and disclose PHI to carry out **treatment, payment, or health care operations** without patient's prior authorization - 45 C.F.R. § 164.506(b)

HIPAA Privacy Rule Expressly Recognizes Health Plans

- **HIPAA Privacy Rule carves out exceptions to the definition of marketing under three categories. The first is directed to health plans:**
  - A communication is not "marketing" if it is made to describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, including communications about:"
    - The entities participating in a health care provider network or **health plan network**;
    - Replacement of, or enhancements to, **a health plan**; and
    - Health-related products or services available only to a **health plan** enrollee that add value to, but are not part of, a plan of benefits.

    http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/marketing/index.html

FCC 2012 TCPA Report & Order

- **FCC acknowledged it "shall consult and coordinate with the [FTC] to maximize consistency with the rule promulgated by the [FTC]" pursuant to the Do-Not-Call Implementation Act, 15 U.S.C. § 6101** - 2012 Report and Order, para. 15 (referring to the TSR, 16 C.F.R. § 310.4(b))
- **Like the TSR amendments, concern among healthcare industry constituents that legitimate/beneficial healthcare messages allowed under HIPAA could be misconstrued as "telemarketing" under the TCPA:**
  - Appointment and prescription refill reminders, etc.
  - Health insurance renewal/payment information
- **FCC agreed with FTC's TSR 2008 Amendment and exempted all Covered Entities and Business Associates under HIPAA for broad range of "health care-related calls" to landline phones – same as FTC**

"[B]ased on the record and the HIPAA requirements, we agree with the FTC approach under the TSR and are persuaded that the HIPAA privacy regulations are rigorous and reflect a statutory mission to protect privacy rights." - 2012 Report and Order, para. 65.

FTC Acknowledged Important HHS & HIPAA Objectives

- *"Congress recognized that the use of advanced communications technology could compromise an individual's privacy interests, and accordingly, directed HHS to promulgate rules that would appropriately balance patient interests in protecting the privacy of their healthcare information with the Congressional 'objective of reducing the administrative costs of providing and paying for healthcare.'"*

- *"One of [HIPAA's] stated goals was to 'improve the efficiency and effectiveness of the health care system by encouraging the electronic transmission of certain health information.'"*

- *"[A]lthough HHS 'originally proposed privacy rules that would not have excluded healthcare communications from their patient authorization requirement,' HHS ultimately concluded, after two full notice and comment rulemaking proceedings, that such a restriction on healthcare communications 'would materially affect the quality and efficiency of healthcare.'"*

- FTC TSR Amendment, 73 Fed. Reg. 51190 (August 29, 2008)

FCC Concurred with FTC's 6-Prong Rationale

"In summary, the Commission has determined to exempt healthcare-related prerecorded message calls subject to HIPAA from the prerecorded call amendment. This determination is based on six primary considerations . . . ."

1. "[D]elivery of healthcare-related prerecorded calls subject to HIPAA **already is regulated extensively** at the federal level."

2. "[C]overage of such calls by the amendment could **frustrate the Congressional intent embodied in HIPAA**, as well as other federal statutes governing healthcare-related programs."

3. "[N]umber of healthcare providers who might call a patient **is inherently quite limited- as is the scope of the resulting potential privacy infringement**--in sharp contrast to the virtually limitless number of businesses conducting commercial telemarketing campaigns."

4. **"[N]o incentive**, and no likely medical basis, for providers who place healthcare-related prerecorded calls to attempt to boost sales through an ever-increasing frequency or volume of calls."

5. "[E]xisting record does not persuade the Commission that it should find that '**the reasonable consumer' would consider prerecorded healthcare calls coercive or abusive**."

6. "FTC law enforcement experience **does not suggest that healthcare-related calls have been the focus of the type of privacy abuses** the amendment is intended to remedy."

- FTC TSR Amendment, 73 Fed. Reg. 51192 (August 29, 2008); *see also* FCC 2012 Report & Order, para. 59.

Additional FTC and FCC Support of Exemption

- "The Commission has determined . . . that healthcare-related prerecorded message calls subject to HIPAA should be exempt, because application of the amendment to such calls '**is not necessary to prevent the unfair or deceptive act or practice [that harms consumer privacy] to which the [amendment] relates.**'"

  - FTC TSR Amendment, 73 Fed. Reg. 51192 (August 29, 2008)

- "Furthermore, we agree with commenters that assert these calls **serve a public interest purpose: to ensure continued consumer access** to health care-related information. … We note at the outset that **HIPAA regulations cover all communications** regarding protected health information and all means of communication regarding such information."

  - FCC 2012 Report & Order, paras. 60-61

FCC 2012 TCPA Report & Order

- **FCC also revised its regulations to include exemption for wireless devices for all Covered Entities and their Business Associates** identical to landline rules, although text of 2012 Report & Order was silent on wireless devices
  - Actual text of FCC TCPA 2012 HIPAA Exemptions from written PEC:
  - **Residential Landline:** *"Delivers a 'health care' message made by, or on behalf of, a '**covered entity' or its 'business associate**,' as those terms are defined in the HIPAA Privacy Rule, 45 C.F.R. §160.103."* 64 C.F.R. § 1200(a)(3)(v).

    Wireless devices or ATDS: *"[D]elivers a 'health care' message made by, or on behalf of, a '**covered entity' or its 'business associate**,' as those terms are defined in the HIPAA Privacy Rule, 45 C.F.R. § 160.103."* 64 C.F.R. § 1200(a)(2)

- **Compare with FTC TSR 2008 Exemption from written prior agreement:**
  - **Residential Landline:** *" This paragraph (v) shall not apply to any outbound telephone call that delivers a prerecorded healthcare message made by, or on behalf of, **a covered entity or its business associate**, as those terms are defined in the HIPAA Privacy Rule, 45 C.F.R. 160.103."* 16 C.F.R. § 310.4(b)(1)(v)(D).

FCC 2015 Declaratory Ruling & Order

- **AAHAM petitioned for clarification and confirmation that provision of telephone number by consumer constitutes PEC also applies to the healthcare industry**
- **Need for clarification and confirmation due to persistent lawsuits against health care providers and health insurance plans (i.e., Covered Entities), despite FCC's previous rulings (and court decisions):**

  - 1992 TCPA Order, para. 31 – *"[P]ersons who knowingly release their phone numbers have in effect given their invitation or permission to be called at the number which they have given, absent instructions to the contrary"*
  - 2008 ACA Int'l Declaratory Ruling, para. 9 – Party who provides wireless number to creditor as part of credit application *"reasonably evidences prior express consent by the cell phone subscriber to be contacted at the number regarding the debt"*
  - 2014 GroupMe Declaratory Order – Affirming 2008 ACA Int'l Declaratory Ruling

FCC 2015 Declaratory Ruling & Order

- **Instead of clarification that clearly applies to all Covered Entities, FCC issued this statement:**

  "We clarify, therefore, that provision of a phone number to a healthcare provider constitutes prior express consent for healthcare calls subject to HIPAA by a HIPAA-covered entity and business associates acting on its behalf, as defined by HIPAA, if the covered entities and business associates are making calls within the scope of the consent given, and absent instructions to the contrary."

- **Could be misinterpreted to require provision of phone number to health care provider and not to any other Covered Entity or its Business Associates**
  - All Covered Entities and Business Associates are covered under FTC's TSR, prior FCC Rules, HIPAA's regulatory scheme, and HIPAA Privacy Rule

Additional Issues

- **2015 Declaratory Order also inconsistent w/ FCC's 2012 Report & Order**
  - 2012 Report & Order and Rules provide important exemption for all HIPAA-related calls for Covered Entities and their Business Associates for messages not classified as marketing under HIPAA
    - FCC example of HIPAA-allowed call now exempt under TCPA Rules: Prerecorded **"health-care related call"** notifying family that student reaching age of majority will lose insurance coverage and offers continuation of coverage. fn 187 (citing to HHS website re: HIPAA Privacy Rule)
  - 2015 Declaratory Order exempts certain non-telemarketing calls but only mentions health care providers, which could be misinterpreted to exclude health plans and health care clearinghouses – who are also Covered Entities under HIPAA

Compare FCC 2012 and 2015 HIPAA Exemptions

- **AAHAM also sought an exemption from PEC for non-telemarketing calls to wireless devices not charged to the called party – partially granted by FCC. Actual text of FCC 2015 HIPAA-related exemption:**

  "***We therefore grant the exemption for calls subject to HIPAA, but limit this exemption by excluding any calls contained therein that include telemarketing, solicitation, or advertising content, or which include accounting, billing, debt-collection, or other financial content.***" Para. 146.

- **The HIPAA Privacy Rule does not have such limitations. "Health care means care, services, or supplies related to the health of an individual . . . . [And] includes, but is not limited to . . ." 45 C.F.R. § 160.103**
- **Compare with 2012 FCC HIPAA-related exemption for HIPAA-allowed calls/texts:**

  "[***"[D]elivers a 'health care' message made by, or on behalf of, a 'covered entity' or its 'business associate,' as those terms are defined in the HIPAA Privacy Rule, 45 C.F.R. § 160.103."*** 64 C.F.R. § 1200(a)(2)

FCC 2015 Declaratory Ruling & Order

- **Why is it important that the FCC confirm that its PEC clarification and limited exemption apply to all Covered Entities and their Business Associates?**
  - Health care providers are just one class of Covered Entities – other Covered Entities provide healthcare-related services and have valid needs to communicate with patients and members, and with other Covered Entities
    - First Amendment issue when identical speech is restricted/prohibited based on speaker
  - Excluding health plans and health care clearinghouses from PEC clarification and exemption is inconsistent with congressional mandate to provide efficient and affordable healthcare
  - Excluding health plans and health care clearing houses encourages increased litigation and regulatory enforcement actions against well-meaning actors – and increases overall costs, also inconsistent with congressional mandate to contain costs

Impact

- **FCC 2015 Declaratory Order was less than clear and therefore, adds unnecessary and unwarranted risks for Covered Entities & Business Associates:**
  - Elimination of certain classes of patients from PHE monitoring and preventive care programs
    - Wireless-only households (cord cutters and low income)
    - Higher risk patients with serious medical problems
    - Senior citizens
    - Chronically ill
  - Increased costs to patients and burdens on health system
  - Reduction in improved health outcomes
  - Breach of contract claims from States and Medicare
  - Regulatory enforcement actions
  - Class action lawsuits

Cost/Risk of Litigation and Covered Entity Response

- **Increased risk is simply not acceptable for some Covered Entities**
  - So far two providers removed wireless numbers from PHE programs
    - National Medicaid plan with 4 million members (gaps in care, appointments)
    - National pharmacy benefit manager with 26 Million members (prescription refills)
  - Negative trend in health outcomes already seen
- **Four more Covered Entities are actively considering discontinuing PHE to wireless numbers**
- **As a practical matter, timely patient support cannot be replaced by live agents**
  - Not just a matter of increased cost, also poor use of live clinical resources
  - Not enough hours in a day or days in a week
  - Not enough qualified resources
- **Covered Entity response and industry/litigation trends indicate a serious need for increased clarity and balance**

Resolution

- **A simple and single change in one phrase will resolve the various issues with FCC's 2015 PEC clarification:**
  - **Change the term "healthcare provider" to "covered entity"**

    "We clarify that therefore, that provision of a phone number to a covered entity constitutes prior express consent for healthcare calls subject to HIPAA by a HIPAA-covered entity and business associates acting on its behalf, as defined by HIPAA"
- **Same change from "healthcare provider" to "covered entity" for non-telemarketing calls made to wireless devices without charge to consumer**
  - Also need to include Covered Entity's Business Associates
- **Clarify fn 473 in 2015 Declaratory Order that messages from health plans are also governed by HIPAA and can be exigent; therefore, are allowed under exemption for non-telemarketing calls**

Benefits

- **FCC 2015 Declaratory Order will then be consistent with:**
  - Congressional intent
  - FCC 1992 TCPA Order
  - FCC 2008 ACA Declaratory Order
  - FCC 2012 TCPA Order
  - FTC TSR 2008 Amendment
  - HIPAA and HIPAA Privacy Rule
  - First Amendment
  - State requirements and contract provisions
  - Federal reporting and follow-up requirements under Medicare

And will serve the public interest by ensuring continued consumer access to health care-related information.

Thank you!