Patient-Centered
Primary Care
COLLABORATIVE

June Policy and Advocacy Call
Tuesday, June11 from 1:00 – 2:00 PM ET
Dial-In Number: (267) 930-4000, Access: 740-654-563

I. Co-Chair Welcome and Introduction *Katie Martin, NPWF*

II. Oral Health and Medicare *Judi Haber, NIIOH*

a. Community Statement on Medicare Coverage for Medically Necessary Oral and Dental Health Therapies (p. 2)
b. Whole Person Care of Older Adults: Through an Interprofessional Lens
    i. Interprofessional Education and Integrated Oral Health Care (p.5)
    ii. PAs are Contributing to Oral Health in Older Adults (p.15)
    iii. Medicare without Oral Health Coverage: Stories (p. 23)
    iv. Oral Health of Older Adults with Cognitive Impairments (p. 32)

III. CMS Patients Over Paperwork RFI *Chris Adamec, PCPCC*

a. RFI Text (p. 38)

IV. PCORI Reauthorization Update *Caitlin McCormick, PCORI*

a. Congressional Letter (p. 50)
b. PCORI Primer for 2019 & Research Funding (p. 57)
c. PCORI Research Highlights & Unique Approach (p. 61)
d. Potential Impact of PCORI Research (65)

V. PCPCC Updates *Chris Adamec, PCPCC*

a. Patient Matching Letter to Congress (p. 70)
b. ADT Information Sharing Letter to CMS (p. 73)
c. Coalition Letter on 21st Century Pediatric EHRs to ONC (p. 77)
d. Geographic Population Based Payment Comment to CMS (p. 79)

VI. Adjournment & Next Call

a. July 17 – Release of PCPCC Evidence Report in DC
b. July Policy/Advocacy Call: Tuesday, July 23, from 1:00 - 2:00 PM ET
c. Homework: Problems with “Primary Care First” and How to Fix Them (p. 81)

Community Statement on Medicare Coverage for
Medically Necessary Oral and Dental Health Therapies

The undersigned organizations are proud to join in support of Medicare coverage for medically-necessary oral/dental health therapies.

It is well established that chronic diseases disproportionately impact Medicare beneficiaries and impose a substantial cost on the federal government. It is also well established that untreated oral microbial infections are closely linked to a wide range of costly chronic conditions, including diabetes, heart disease, dementia, and stroke. In addition, oral diseases have been documented by researchers and medical specialty societies as precluding, delaying, and even jeopardizing medical treatments such as organ and stem cell transplantation, heart valve repair or replacement, cancer chemotherapies, placement of orthopedic prostheses, and management of autoimmune diseases.

Despite these factors, most Medicare beneficiaries do not currently receive oral/dental care even when medically necessary for the treatment of Medicare-covered diseases. In fact, Medicare coverage extends to the treatment of all microbial infections except for those relating to the teeth and periodontium. There is simply no medical justification for this exclusion, especially in light of the broad agreement among health care providers that such care is integral to the medical management of numerous diseases and medical conditions. Moreover, the lack of medically necessary oral/dental care heightens the risk of costly medical complications, increasing the financial burden on Medicare, beneficiaries, and taxpayers.

A number of major insurance carriers provide medically-necessary oral and dental coverage to targeted enrollees with conditions such as diabetes, heart disease, stroke, head/neck cancers, and transplants. According to some reports, such coverage has realized important benefits, including markedly lower hospitalization and emergency department admission rates as well as substantial cost reductions. On a further note, veterans getting care through the Veterans Health Administration receive medically adjunctive oral/dental treatment in many instances when a dental diagnosis affects their medical prognosis. These are all important steps forward, and medically necessary oral/dental healthcare should be provided in traditional Medicare as well.

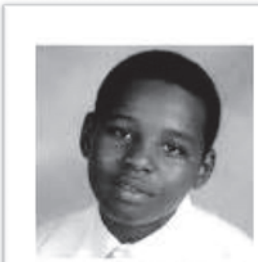
The Medicare program and all its beneficiaries should not be without the vital clinical and fiscal benefits of coverage for medically necessary oral/dental health therapies. Given the significant potential to improve health outcomes and reduce program costs, we urge Congress and the Administration to explore options for extending such evidence-based coverage for all Medicare beneficiaries.

AARP
Acuity Specialists
Adenoid Cystic Carcinoma Research Foundation
AIDS Foundation of Chicago
Allies for Independence
American Academy of Maxillofacial Prosthetics
American Academy of Nursing
American Academy of Periodontology
American Association for Dental Research
American Association of Clinical Endocrinologists
American Association of Colleges of Nursing
American Association of Diabetes Educators
American Association of Hip and Knee Surgeons
American Association of Kidney Patients
American Association of Oral and Maxillofacial Surgeons
American Association of Nurse Practitioners
American Autoimmune Related Diseases Association
American College of Cardiology
American College of Emergency Physicians
American College of Gastroenterology
American College of Physicians
American College of Prosthodontists
American College of Rheumatology
American Dental Association
American Dental Education Association
American Dental Hygienists' Association
American Diabetes Association
American Geriatrics Society
American Head and Neck Society
American Kidney Fund
American Liver Foundation
American Network of Oral Health Coalitions
American Nurses Association
American Parkinson Disease Association
American Psychiatric Association
American Public Health Association
American Society for Radiation Oncology
American Society of Clinical Oncology
American Society of Nephrology
American Society of Transplant Surgeons
American Society of Transplantation
American Thoracic Society
Arcora Foundation
Arthritis Foundation
Association of Community Cancer Centers
Association of Dental Support Organizations
Association of State and Territorial Dental Directors
Autistic Self Advocacy Network
Brain Injury Association of America
California Dental Association
California Medical Association
Catholic Health Association of the United States
Center for Health Law and Policy Innovation
Center for Medicare Advocacy
Children's Dental Health Project
Cornerstone Dental Specialties
Crohn's and Colitis Foundation of America
Dental Lifeline Network
Dental Trade Alliance
DentaQuest Partnership for Oral Health Advancement
Disability Rights Education and Defense Fund
Eating Disorders Coalition
Epilepsy Foundation
Families USA
Georgia AIDS Coalition
Gerontological Advanced Practice Nurses Association
Hartford Institute for Geriatric Nursing
Head and Neck Cancer Alliance
Henry Schein Cares Foundation
HIV Medicine Association
International Pemphigus and Pemphigoid Foundation
John A. Hartford Foundation
Justice in Aging
Leukemia and Lymphoma Society
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Medicare Rights Center
Mending Hearts
Mental Health America
National Alliance of State & Territorial AIDS Directors
National Alliance on Mental Illness
National Association of Area Agencies on Aging
National Association of Community Health Centers
National Association of Dental Plans
National Association of Nutrition and Aging Services Programs
National Association of Social Workers
National Association of States United for Aging and Disabilities
National Comprehensive Cancer Network
National Committee to Preserve Social Security and Medicare
National Council for Behavioral Health
National Forum for Heart Disease and Stroke Prevention

National Health Law Program
National Interprofessional Initiative on Oral Health
National Kidney Foundation
National League for Nursing
National Multiple Sclerosis Society
National Network for Oral Health Access
National Osteoporosis Foundation
National Rural Health Association
National Stroke Association
Oral Cancer Foundation
Oral Health America
Oral Health Nursing Education and Practice Program
Pacific Dental Services Foundation
Parkinson's Foundation
Patient-Centered Primary Care Collaborative
PEW Dental Campaign
Preventive Cardiovascular Nurses Association
ProHEALTH Dental
Renal Physicians Association
Santa Fe Group
School-Based Health Alliance
Scleroderma Foundation
Sjogren's Syndrome Foundation
Society for Transplant Social Workers
Support for People with Oral and Head and Neck Cancer
The AIDS Institute
The Arc of the United States
The Gerontological Society of America
The Michael J. Fox Foundation
The Society for Thoracic Surgeons
The TMJ Association

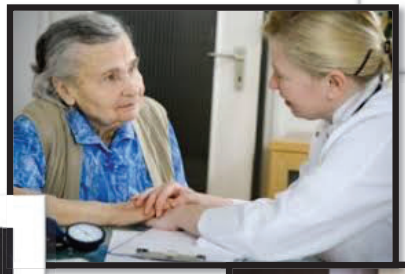
National *Interprofessional Initiative* on Oral Health

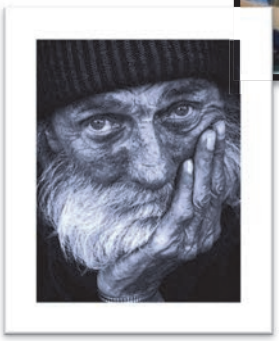
engaging clinicians, eradicating dental disease



Deamonte Driver, 12
Died February 25, 2007

A **Systems** Change Initiative
Advancing Interprofessional Education
and Integrated Oral Health Care





Anita Duhl Glicken, MSW
Executive Director, NIIOH
Associate Dean and Professor Emerita
University of Colorado Anschutz Medical Campus
Anita.Glicken@niioh.org

Initiative activities are made possible as a result of funding from the DentaQuest Partnership for Oral Health Advancement and the Arcora Foundation

How Did We Get Here?

108 Million

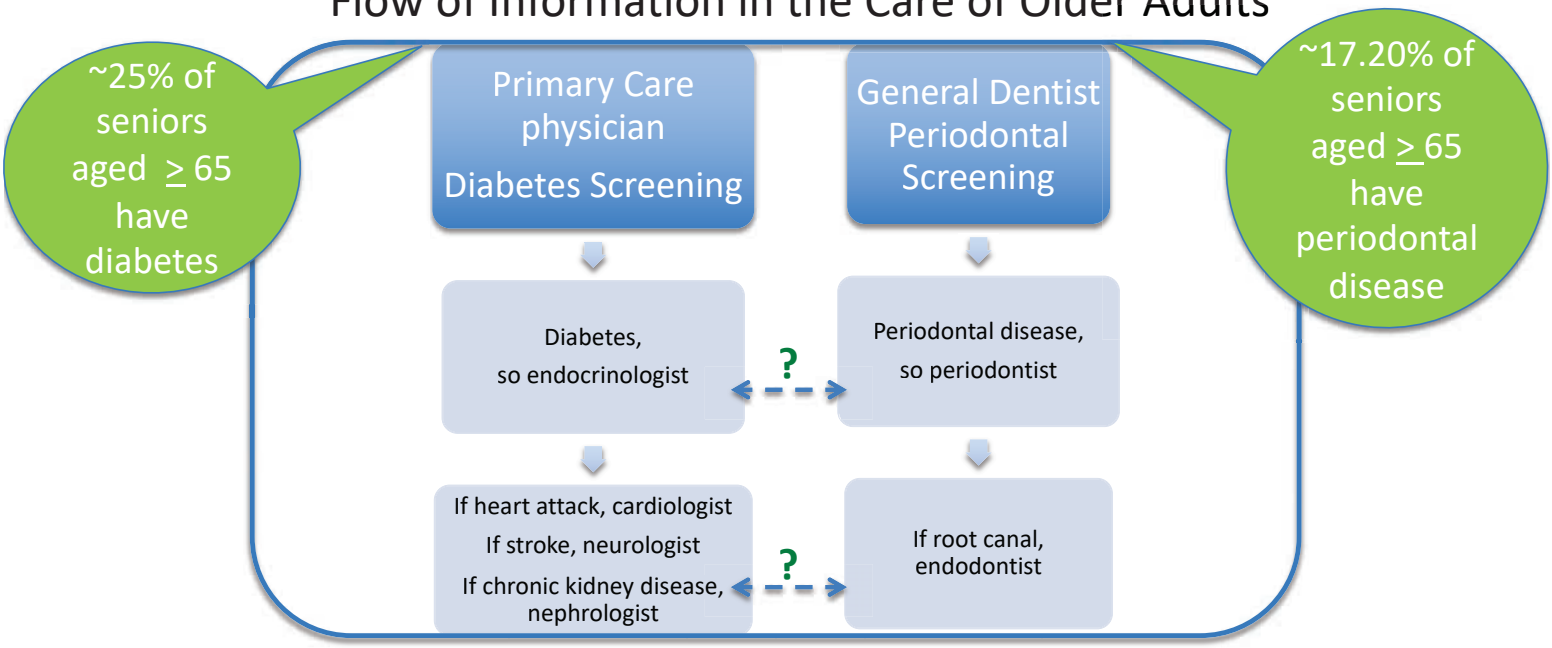
People visit a medical provider but not a dental provider

27 Million

Visit a dental provider but not a medical provider

Vujicic, M., H. Israelson, J. Antoon, R. Kiesling, T. Paumier, and M. Zust. 2014. A profession in transi- tion. Guest editorial. Journal of the American Den- tal Association 145(2):118-121.

Flow of Information in the Care of Older Adults



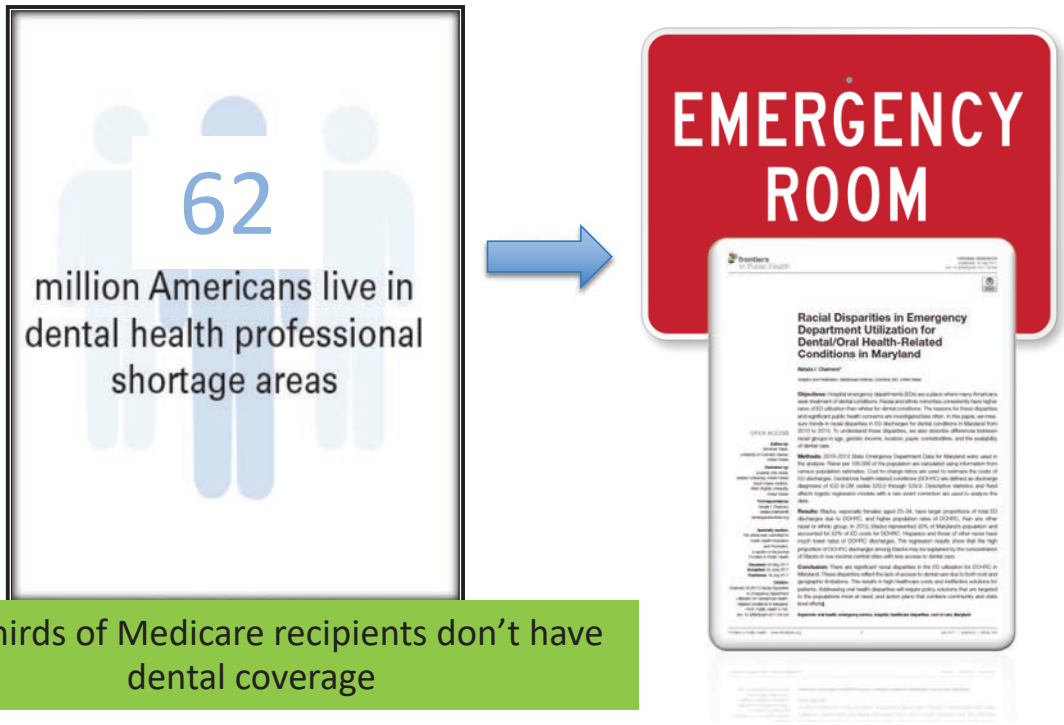
Communication is tenuous, usually carried out by patient, if at all

Adapted from Powell and Din 2008

The Oral Health Needs of Oral Health of Older Adults (≥ 65)?

- Nearly 1 in 5 have untreated tooth decay
- About 2 in 3 (68%) have gum disease
- Nearly 1 in 5 are edentulous
- Most take both prescription and over the counter drugs, which can cause dry mouth increasing risk of cavities
- The median age of oral cancer diagnosis is 62

Health Professional Shortage Areas



Two-thirds of Medicare recipients don't have dental coverage

Who, What and Why – NIIOH 2009

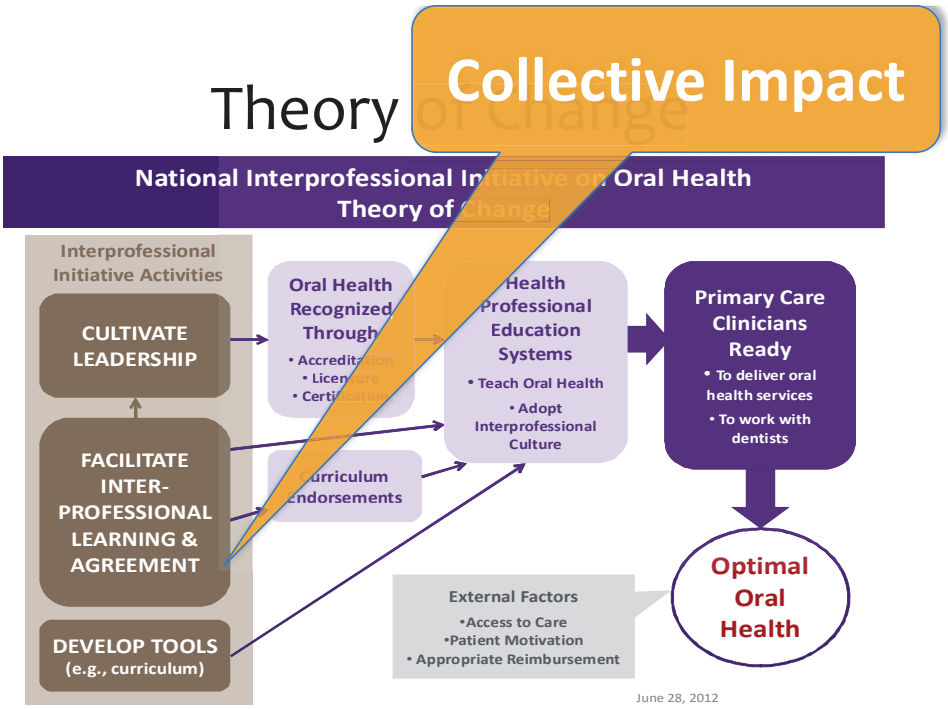
Consortium:	*Funders, health professionals +national organizations*
Vision:	*Eradicate dental disease*
Mission:	*Engage primary care team*
Focus:	*Integrate oral health into primary care education + practice*

The Short Answer

NIIOH is a systems change initiative that provides "Backbone Support" and facilitates interprofessional agreement and alignment to ready an interprofessional oral health workforce for whole person care

The Opportunity for Change

Theory of Change



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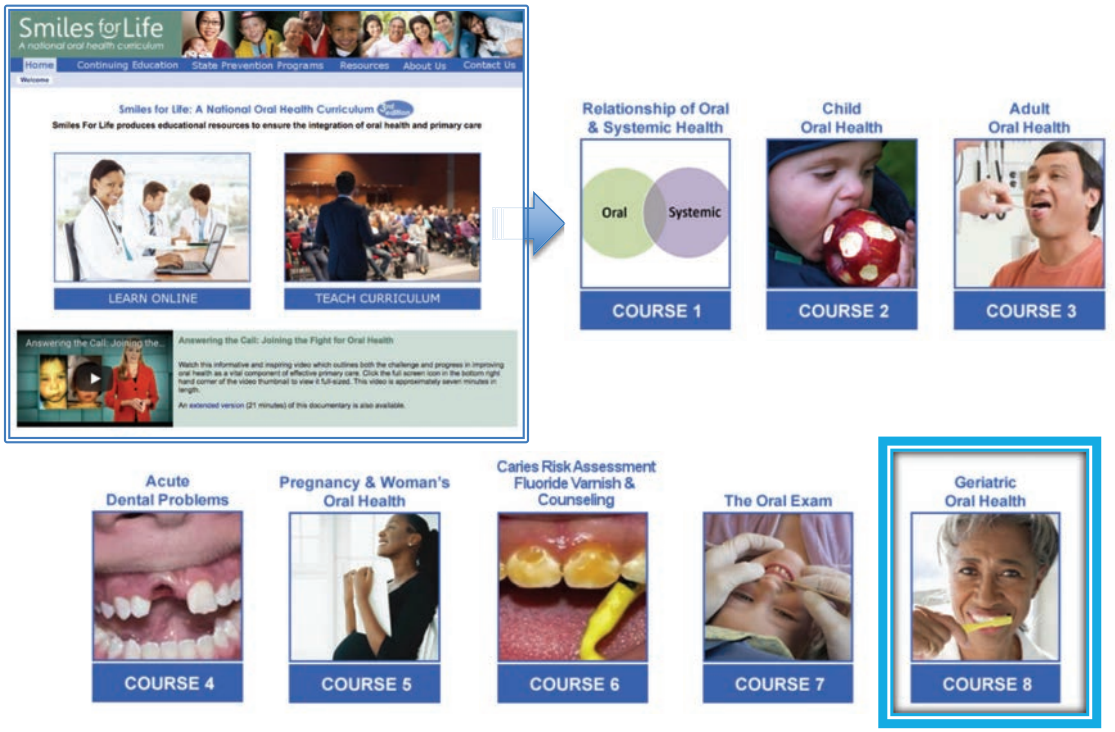
Support, align and connect partner efforts to integrate oral health into education and practice.

Smiles For Life



Resources

Facilitate Interprofessional Agreement

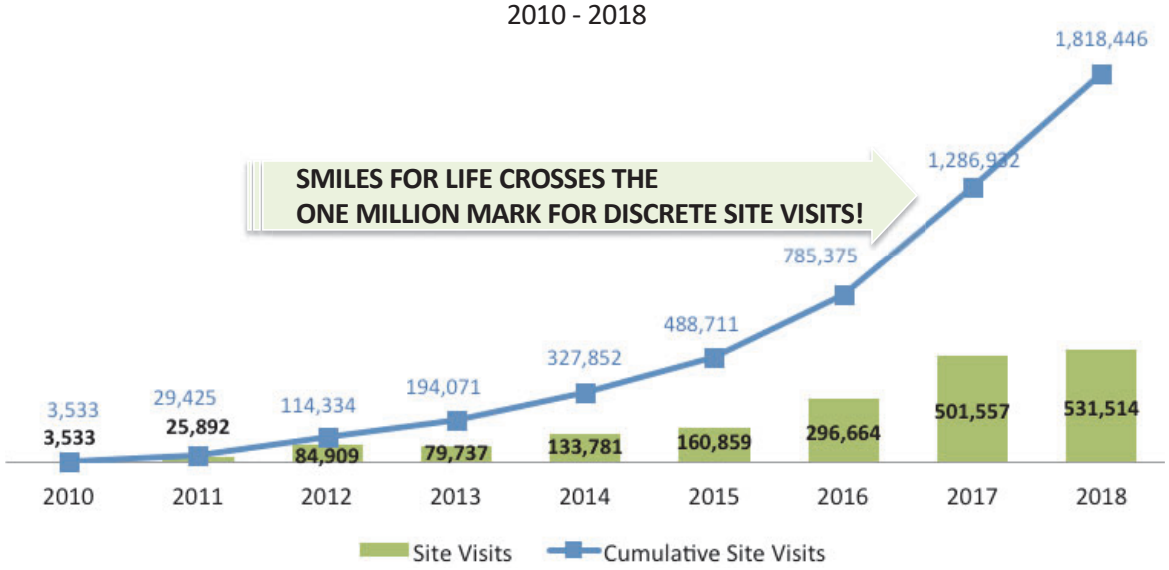
20

Endorsing organizations representing

Medicine
PA's
Nursing
Dentistry
Dental Hygiene
Pharmacy
Community Health Centers
And More!

Smiles for Life Discrete Site Visits[1]

Discrete Site Visits
2010 - 2018



Since the site launched in June 2010, there have been:

- **102,082** registered users
- **299,0412** courses completed for CE credit
- **51,872** modules downloaded by educators

Smiles for Life Survey

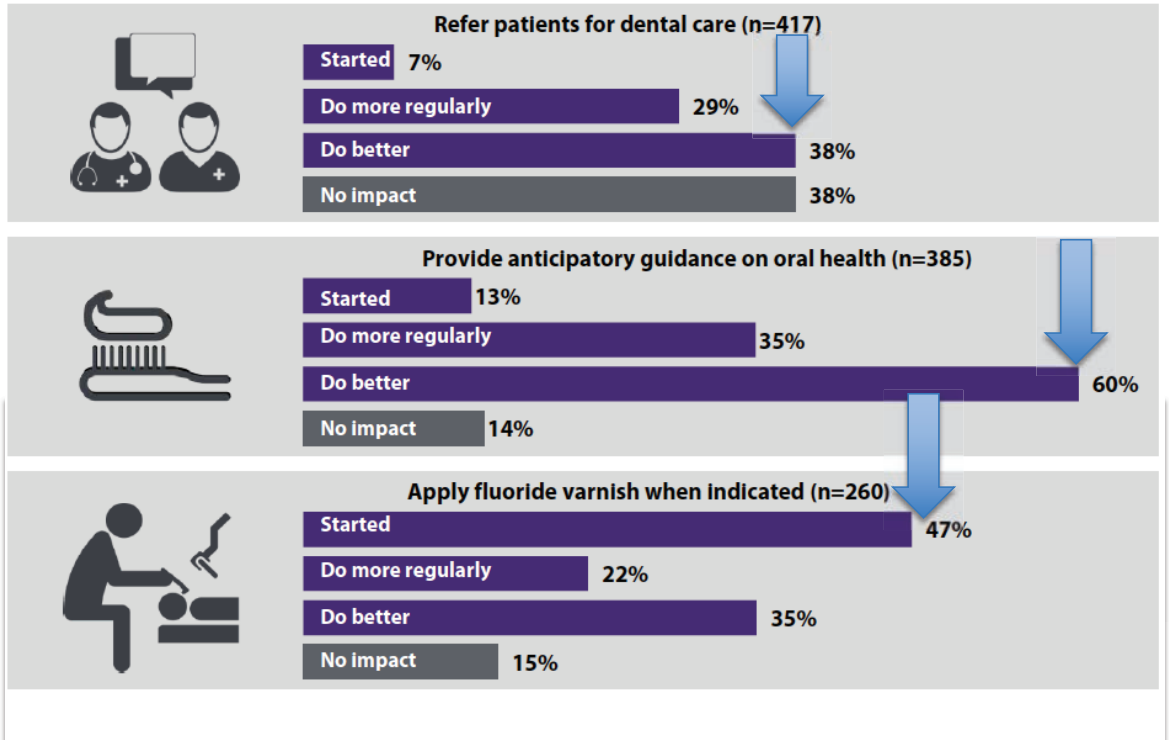
Key Question:

- How does Smiles for Life influence practice?
  - Providers reported that SFL influenced their practice of oral health activities in one or more of the following ways:
    - Led them to start performing oral health activities
    - Allowed them to perform oral health activities more regularly
    - Helped them perform oral health activities better

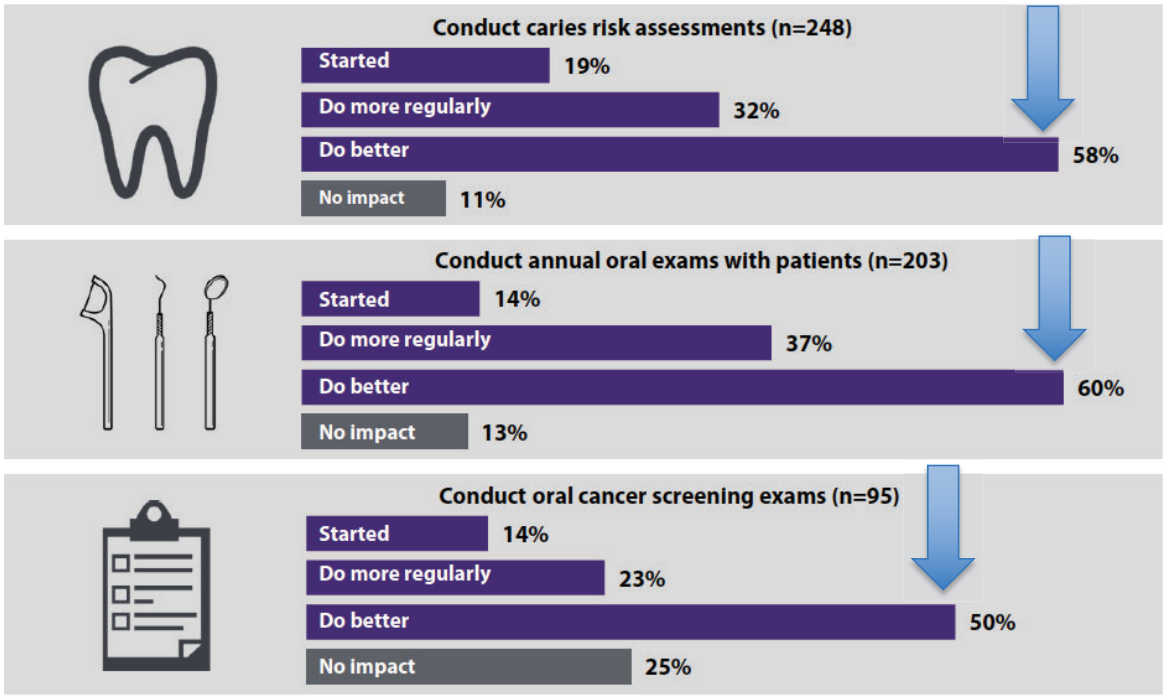
Clark M, Quinonez R, Bowser J, Silk H (2017). Curriculum influence on interdisciplinary oral health education and practice. *Journal Public Health Dentistry.* 2017 Jun; 77(3):272-282. doi: 10.1111/jphd.12215.

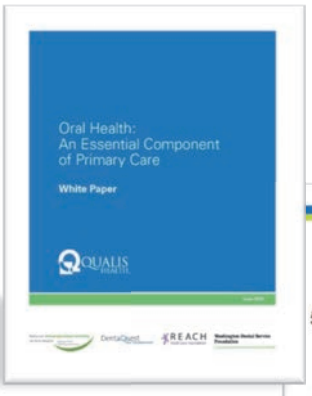
National *Interprofessional Initiative* on Oral Health

Influence on 6 Key Activities



Influence on 6 Key Activities

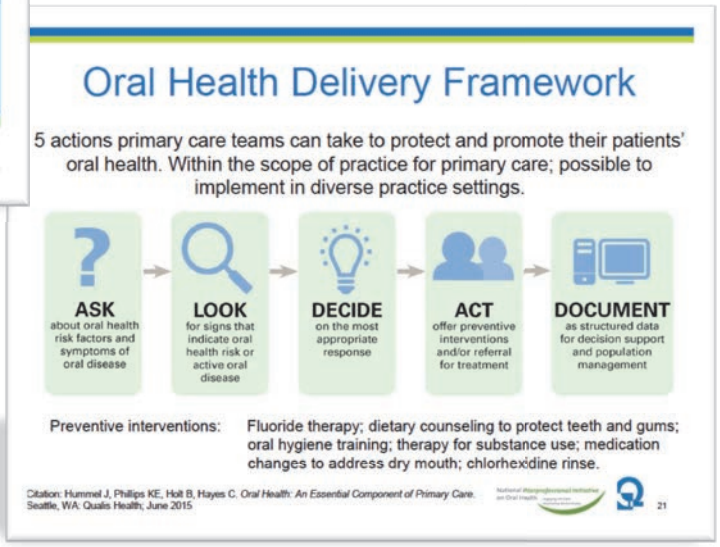




Oral Health: An Essential Component of Primary Care

Published

June 2015



Field-Testing a Conceptual Framework

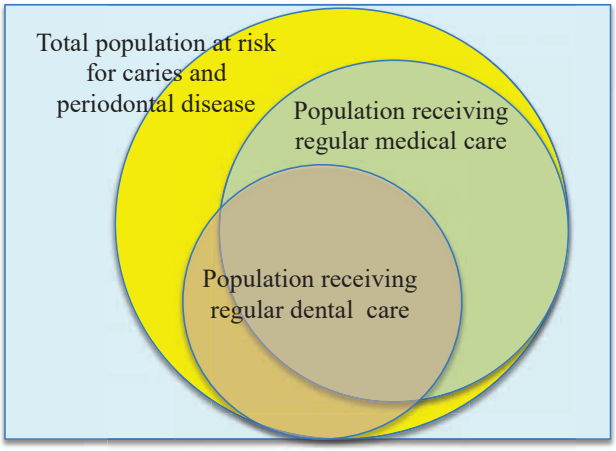
Develop **Test** **Improve** **Disseminate**

19 diverse healthcare delivery organizations: Private practices, Federally Qualified Health Centers; medical only and on-site dental

Adults with diabetes (12), pediatrics (5), pregnancy (1), adult well visits (1)

eCW (5), EPIC (8), NextGen (2), Centricity (2), Success EHS (2)

Using population health to address "missed opportunities"



National Interprofessional Initiative on Oral Health

Field-Testing Results Informed the Creation of the Implementation Guide and Tools

"Oral Health Integration Implementation Guide"

Toolkit for primary care teams (Released 10/10/16)

What's in the Guide?

- Workflow maps
- Referral agreements
- Patient engagement strategies
- Patient/family education resources
- EHR templates
- Case examples
- Impact data and more

Resources available at:
http://www.safetynetmedicalhome.org/change-concepts/organized-evidence-based-care/oral-health

National Interprofessional Initiative on Oral Health

What we have learned

- Organizational change process requires **system-wide intervention**
- Having the **right people, right place, right reason** can change ideas and practice
- A key is having the **right tools and strategies** to impact knowledge, skills and attitudes of providers
- We cannot achieve our vision of **"oral health for all"** unless we change our approach to oral health care
- **Integration and collaboration is key**, we can't do this alone

19

Where Do We Go From Here?

We need to move beyond symptoms of health disparities to aiming policy and funding at changing the structure that creates those disparities

We need to continue to work together to create a shared vision for whole person care across medical and dental silos and define shared performance measures that can catalyze new evaluation strategies with a focus on prevention, value and population health.

Many Thanks to Our Legacy Funders

ARCORA

DentaQuest

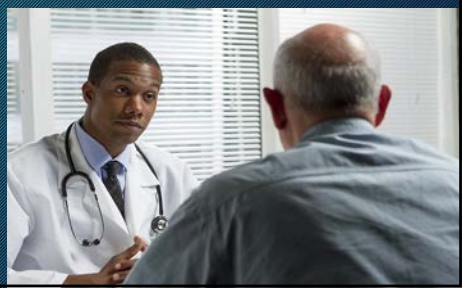
PAs are Contributing to Oral Health in Older Adults

Anthony A. Miller, M.Ed., PA-C
Distinguished Professor & Director
Division of Physician Assistant Studies
Shenandoah University
Winchester, VA

1

Why PAs?

- Provide Primary Care and Practice in Nearly Every Medical Specialty
- PAs Value Interprofessional Practice
- High Patient Satisfaction and Trust
- PAs Focus on Prevention and Health Promotion
- Increasing role in health care leadership roles & change agents
- Specific Focus on Oral Health
  - Screening and Risk Assessment
  - Understand oral – systemic connection
  - Educating Patients on Self Assessment and Good Habits
  - Applying Fluoride Varnish
  - Referrals for Dental Care



2

PA Impact on Health Care

Over 131,000 Certified PAs

Licensed to Practice and Prescribe in all 50 States and DC

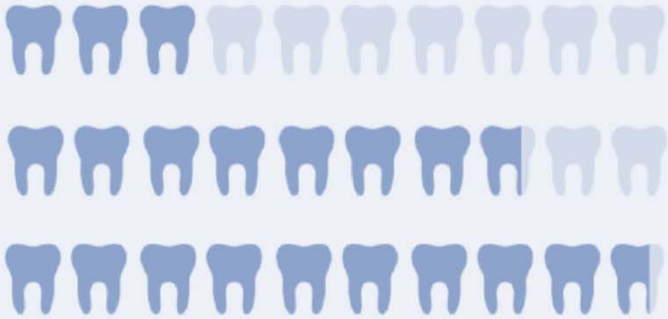
3

The PA Profession Commitment
Leveraging Collective Impact

- Education – oral health integrated in all PA programs
- Smiles for Life - endorsers
- Programs and Research Support – nccPA Health Foundation & PA Foundation
- Research & Publication: JAAPA & JPAE
- Certification – examination content & quality improvement initiatives for recertification
- Continuing Education

4

Growth of Oral Health Education and Training in PA Programs



2008: 32.8% of responding PA programs provided oral health instruction*

2014: 78.4% of responding PA programs provided oral health instruction*

2017: 96% of responding PA programs provided oral health instruction*

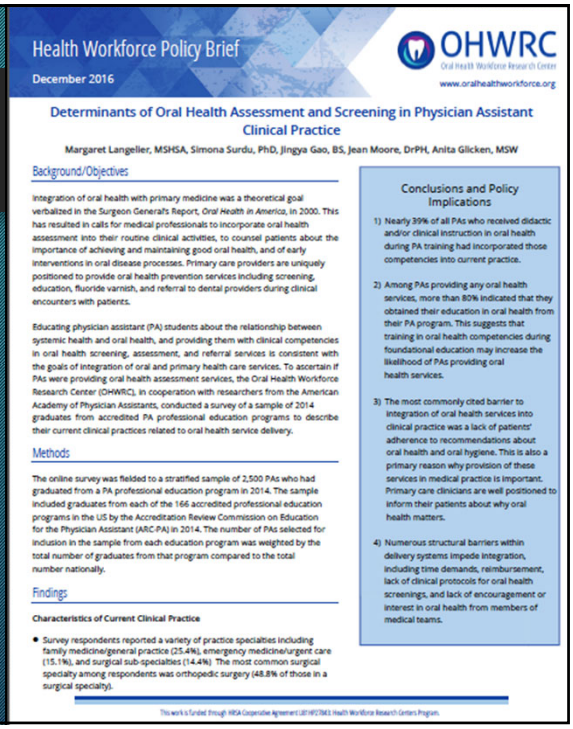
Efforts to integrate oral health into PA curriculum are working, and educating a new generation of providers to view oral health as integral to overall health.

*Response % for each year represents different surveys.

5

2016 Research

PAs who received education in oral health and disease were ~ 2.79 times more likely (95% CI=1.39-5.59, P=0.0038) **to provide oral health services in their clinical practice, compared to those who did not receive any education in oral health competencies.**



Health Workforce Policy Brief

December 2016

OHWRC Oral Health Workforce Research Center www.oralhealthworkforce.org

Determinants of Oral Health Assessment and Screening in Physician Assistant Clinical Practice

Margaret Langeller, MSHSA, Simona Surdu, PhD, Jingya Gao, BS, Jean Moore, DrPH, Anita Glicken, MSW

Background/Objectives

Integration of oral health with primary medicine was a theoretical goal verbalized in the Surgeon General's Report, *Oral Health in America*, in 2000. This has resulted in calls for medical professionals to incorporate oral health assessment into their routine clinical activities, to counsel patients about the importance of achieving and maintaining good oral health, and of early interventions in oral disease processes. Primary care providers are uniquely positioned to provide oral health prevention services including screening, education, fluoride varnish, and referral to dental providers during clinical encounters with patients.

Educating physician assistant (PA) students about the relationship between systemic health and oral health, and providing them with clinical competencies in oral health screening, assessment, and referral services is consistent with the goals of integration of oral and primary health care services. To ascertain if PAs were providing oral health assessment services, the Oral Health Workforce Research Center (OHWRC), in cooperation with researchers from the American Academy of Physician Assistants, conducted a survey of a sample of 2014 graduates from accredited PA professional education programs to describe their current clinical practices related to oral health service delivery.

Methods

The online survey was fielded to a stratified sample of 2,500 PAs who had graduated from a PA professional education program in 2014. The sample included graduates from each of the 166 accredited professional education programs in the US by the Accreditation Review Commission on Education for the Physician Assistant (ARC-PA) in 2014. The number of PAs selected for inclusion in the sample from each education program was weighted by the total number of graduates from that program compared to the total number nationally.

Findings

Characteristics of Current Clinical Practice

- Survey respondents reported a variety of practice specialties including family medicine/general practice (25.4%), emergency medicine/urgent care (15.1%), and surgical sub-specialties (14.4%) The most common surgical specialty among respondents was orthopedic surgery (48.8% of those in a surgical specialty).

Conclusions and Policy Implications

1) Nearly 39% of all PAs who received didactic and/or clinical instruction in oral health during PA training had incorporated those competencies into current practice.

2) Among PAs providing any oral health services, more than 80% indicated that they obtained their education in oral health from their PA program. This suggests that training in oral health competencies during foundational education may increase the likelihood of PAs providing oral health services.

3) The most commonly cited barrier to integration of oral health services into clinical practice was a lack of patients' adherence to recommendations about oral health and oral hygiene. This is also a primary reason why provision of these services in medical practice is important. Primary care clinicians are well positioned to inform their patients about why oral health matters.

4) Numerous structural barriers within delivery systems impede integration, including time demands, reimbursement, lack of clinical protocols for oral health screenings, and lack of encouragement or interest in oral health from members of medical teams.

This work is funded through HRSA Cooperative Agreement UB1HP27861 Health Workforce Research Centers Program.

6

Demographic Drivers

7

"Every day, millions of people with chronic diseases struggle to manage their symptoms. About 80% of older adults have at least one chronic disease, and 68% have at least two. Chronic diseases place a significant burden on individuals as well as health care systems.

National Council on Aging, 2019

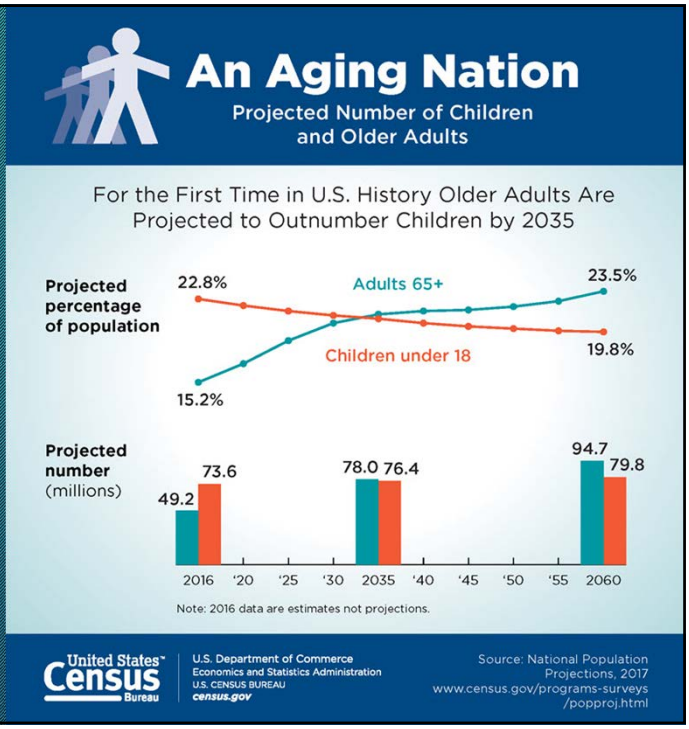


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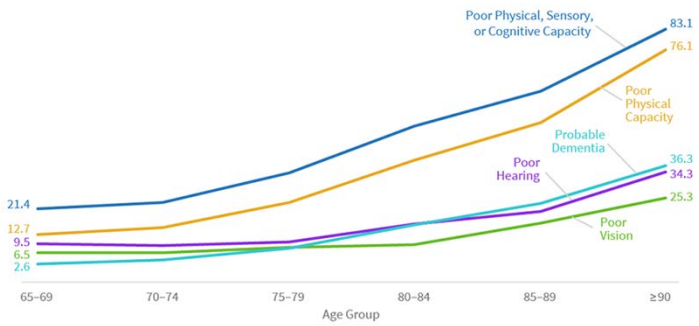
FIGURE 7

The Likelihood of Having a Disability Increases With Age

Age-Specific Estimates of Poor Physical, Sensory, and Cognitive Capacity, Adults Ages 65 and Older (%), 2015

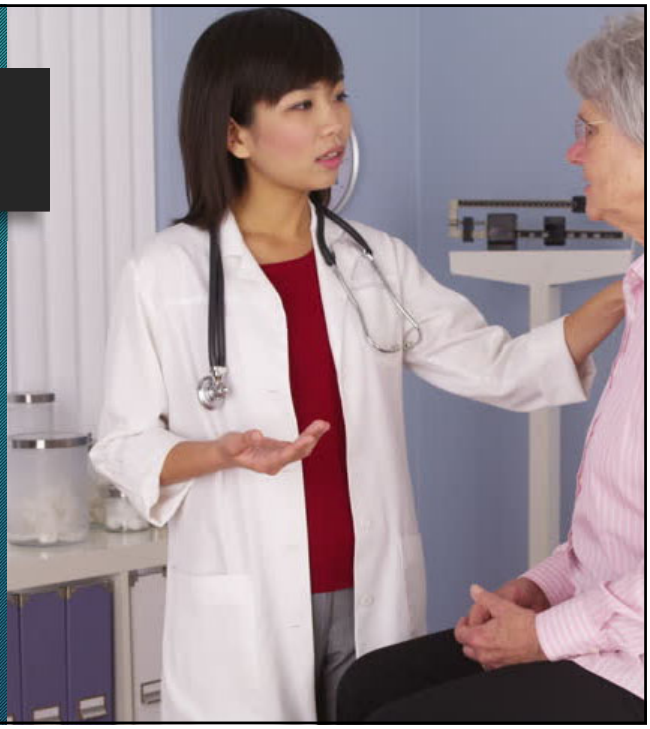


Source: National Health and Aging Trends Study.

9

Data Imperatives

- Nearly 19% of adults age 65 and over have complete tooth loss
- Oral and pharyngeal cancers are often diagnosed late
- Nearly 63 million Americans live in dental health profession shortage areas
- Significant decreased dental visits based on race, disability, poverty, geographic region and population density
- Dental caries and periodontal disease are among the most common chronic conditions
- Dental conditions such as caries and tooth loss impact nutrition, self-esteem, general health



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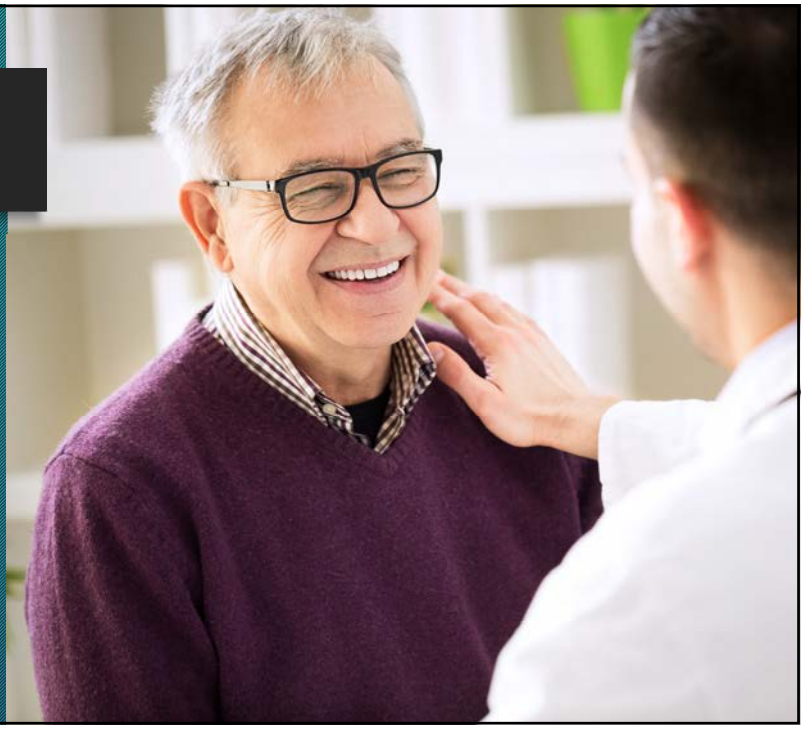
PAs Understand the Connection of Oral Health and Disease

- Oral and pharyngeal cancer
- Diabetes & link to periodontal disease
- Poor oral health link to cardiovascular disease including endocarditis and stroke
- Impact of common medications
- Poor oral hygiene – poor outcomes in aspiration pneumonia
- Mental health impact on oral health and vice versa
- Link of poor oral hygiene and use of tobacco products to poor health outcomes



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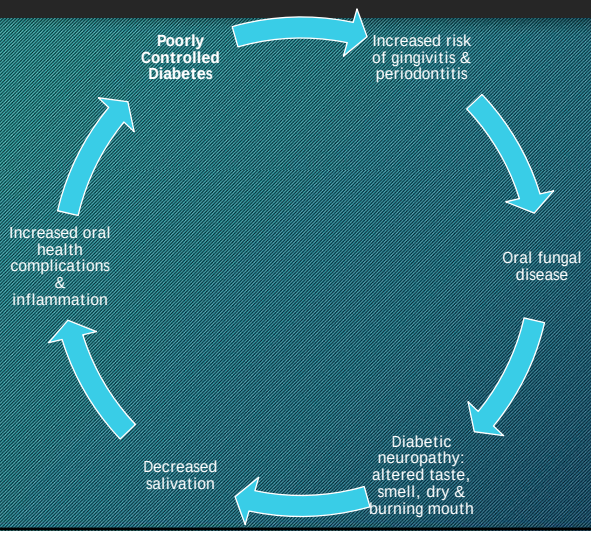
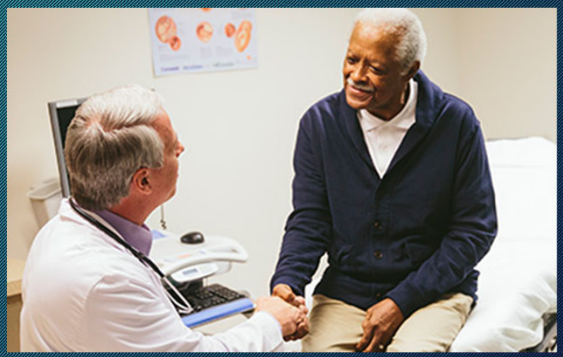
Oral – Systemic Connection





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Recommended Goals

- **Interprofessional healthcare teams should work together on behalf of older adults to improve quality of life and self image by:**
- Advocating for public policies that improve oral health access and funding.
- Assessing and effectively treating oral health conditions that impact overall health and well-being.
- Educating patients on health promotion and disease prevention.

13

Conclusions

- PAs working in team-based practices are impacting oral health and its sequelae for older adults
- Patient trust and confidence in PAs positions them to have positive impact on preventive care outcomes for older adults
- PAs continue to develop referral networks with dentists and other dental care providers
- Positive oral health initiatives can reduce morbidity and mortality for diseases and conditions not directly associated with the oral cavity
- Health care financing is shifting from fee for service to outcomes and quality focus
- PAs have demonstrated they are able to rapidly respond to new markets and research

14

Resources

- Atchison, K., Glicken, A., & Haber, J. Developing an interprofessional oral health education system that meets the needs older adults. Journal California Dental Association. April 2019, 247-256.
- American Academy of Physician Assistants (www.aapa.org)
- Glicken A. et al. Integrating oral health: Physician assistant education in 2017. JPAE (pre-publication 2019).
- Langellar, M. et al. Determinants of oral health assessment and screening in physician assistant clinical practice. Oral Health Workforce Research Center, December 2016.
- NCCPA Health Foundation (www.nccpahealthfoundation.net)
- National Commission on Certification of Physician Assistants (www.nccpa.net)
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- Scommegna, P, Mather, M. & Kilduff, L. Eight demographic trends transforming America's older population. Population Reference Bureau. (www.prb.org)
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- US Census Bureau. Older people projected to outnumber children for first time in U.S. history. March 13, 2018. (https://www.census.gov/newsroom/press-releases/2018/cb18-41-population-projections.html)

15

Medicare without Oral Health Coverage:
Stories from the Front Lines

Hugh Silk, MD, MPH
University of Massachusetts Medical School
Department of Family Medicine and Community Health

Santa Fe Group Meeting
May 2019

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1

Disclosure

- CIPCOH work is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under grant number UH1HP29962, titled Academic Units for Primary Care Training and Enhancement for grant amount $3,500,000. This information or content and conclusions are those of the author and should not be construed as the official position or policy of, nor should any endorsements be inferred by HRSA, HHS or the U.S. Government.
- Also discussing other HRSA work and Qualis work.

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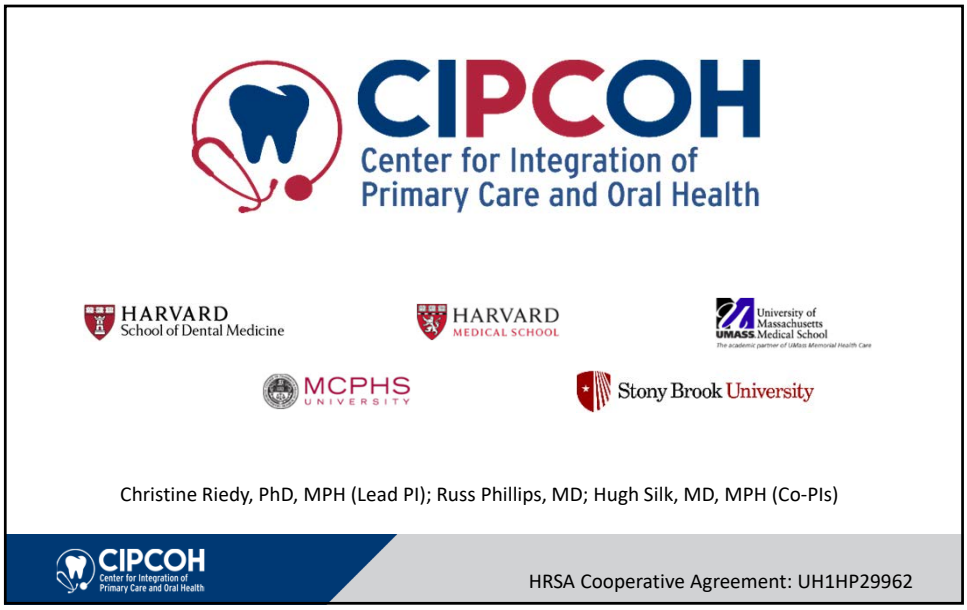
2


CIPCOH
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Primary Care and Oral Health
HARVARD
School of Dental Medicine
HARVARD
MEDICAL SCHOOL
University of
Massachusetts
UMASS Medical School
MCPHS
UNIVERSITY
Stony Brook University
Christine Riedy, PhD, MPH (Lead PI); Russ Phillips, MD; Hugh Silk, MD, MPH (Co-PIs)
CIPCOH
Center for Integration of
Primary Care and Oral Health
HRSA Cooperative Agreement: UH1HP29962

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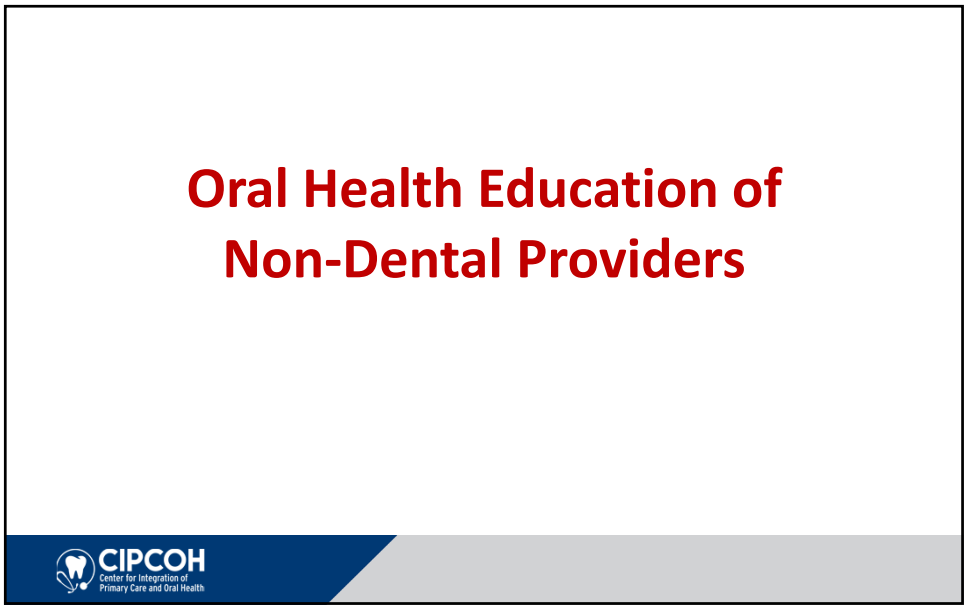
Oral Health Education of
Non-Dental Providers
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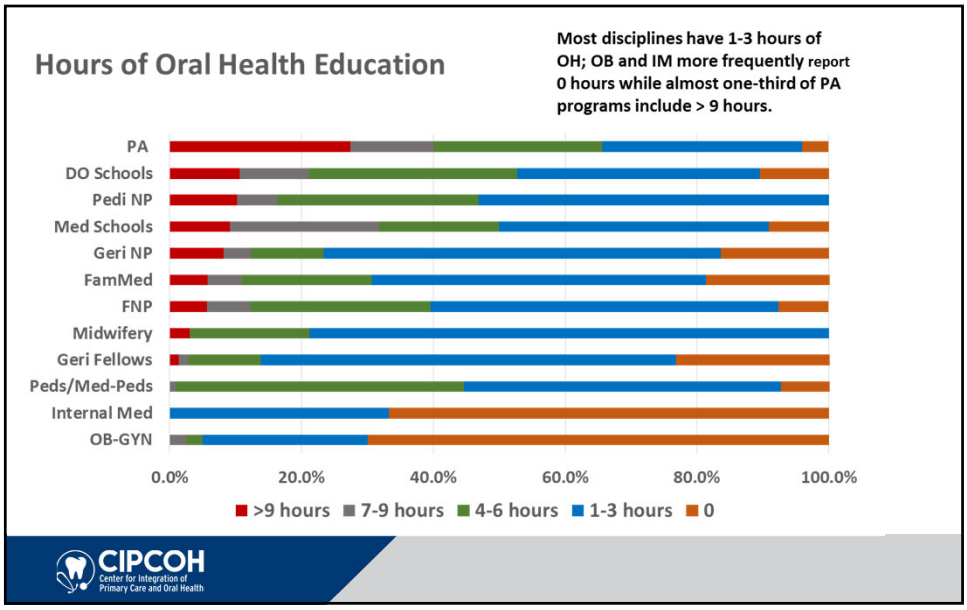
4


Hours of Oral Health Education
Most disciplines have 1-3 hours of OH; OB and IM more frequently report 0 hours while almost one-third of PA programs include > 9 hours.
PA
DO Schools
Pedi NP
Med Schools
Geri NP
FamMed
FNP
Midwifery
Geri Fellows
Peds/Med-Peds
Internal Med
OB-GYN
0.0%
20.0%
40.0%
60.0%
80.0%
100.0%
>9 hours
7-9 hours
4-6 hours
1-3 hours
0
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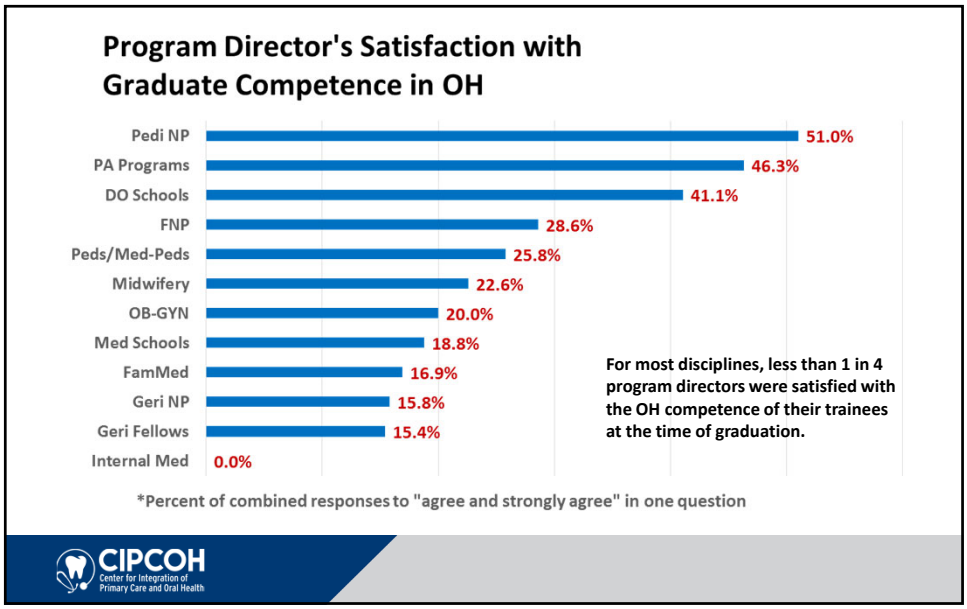
5


Program Director's Satisfaction with Graduate Competence in OH
Pedi NP 51.0%
PA Programs 46.3%
DO Schools 41.1%
FNP 28.6%
Peds/Med-Peds 25.8%
Midwifery 22.6%
OB-GYN 20.0%
Med Schools 18.8%
FamMed 16.9%
Geri NP 15.8%
Geri Fellows 15.4%
Internal Med 0.0%
For most disciplines, less than 1 in 4 program directors were satisfied with the OH competence of their trainees at the time of graduation.
*Percent of combined responses to "agree and strongly agree" in one question
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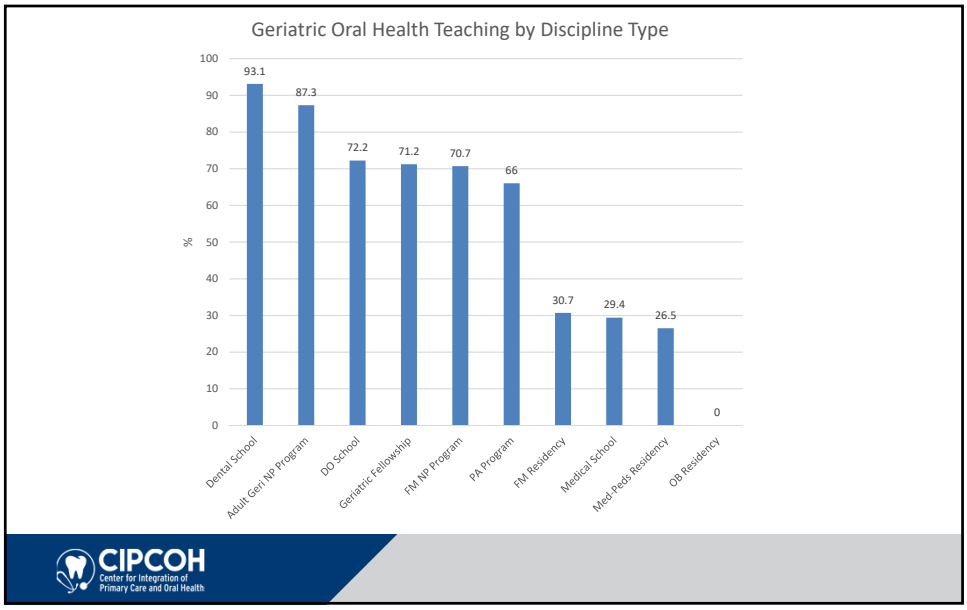
6



7

1st Conclusion

- 111 million people won't see a dentist this year including 30+ million seniors
- Medical providers have not been trained well enough to address this, yet…

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As we get the dental Medicare benefit…
a few programs that can help

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9

Dine with Dentists

Topics covered

- HPV and Oral Cancer
- Opioid Crisis
- *Working Together*
- Easy to do geriatric theme

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Evaluation

1	How much do you perceive that dental colleagues are interested in overall health of patients
2	How important do you feel good oral health is for the overall health of your patients
3	How would you rate your skill level to counsel patients on oral health
4	How would you rate your skill level to examine and assess a patient's mouth
5	How would you rate your awareness of local dentists and the details of making referrals to them
6	How would you rate your current ability to communicate with local dentists
7	How confident are you currently that your patients will get timely referrals to dental colleagues?
1	How much do you percienve that your medical colleagues are interested in oral healht of their paitents
2	How important do you feel that your medical colleagues believe good oral health contributes to overall health of their patients
3	How would you rate your skill level to teach medical colleagues about oral health (oral hygiene, diet, FV)
4	How would you rate your awareness of local medical offices and the details of making and accepting referrals to/from them
5	How would you rate your current ability to communicate with your local medical colleagues
6	How confident are you currently that your medical colleagues feel comfortable making routine referrals to your office

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MD/DOs

	Average
PRE QUESTIONS	
1	7.5
2	9.0
3	6.3
4	6.3
5	4.6
6	4.2
7	3.9
POST QUESTIONS	
1	8.5
2	9.1
3	6.6
4	6.7
5	7.6
6	6.1
7	6.6

Referrals
Communicate

Dentists

Dentist Evals

PRE QUESTIONS	Average
1	6.5
2	7.6
3	8.4
4	5.3
5	6.7
6	6.0
POST QUESTIONS	
1	8.3
2	8.3
3	8.4
4	7.2
5	7.6
6	7.1

interest

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- Reps from:
  - ENT, Oncology, OB/GYN, Geriatrics
  - Primary Care – Fam Med, Peds, Medicine
  - Dentistry – MDS, HSDM, Medicaid
- Projects:
  - updates of oral health for MDs (e.g. geriatric OH messaging)
  - ED-Dental collaboration
  - State wide survey
  - Video and public messaging

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State Level Advocacy

ORAL HEALTH OHAT ADVOCACY TASKFORCE

- Oral Health Coalition (only one in the US)

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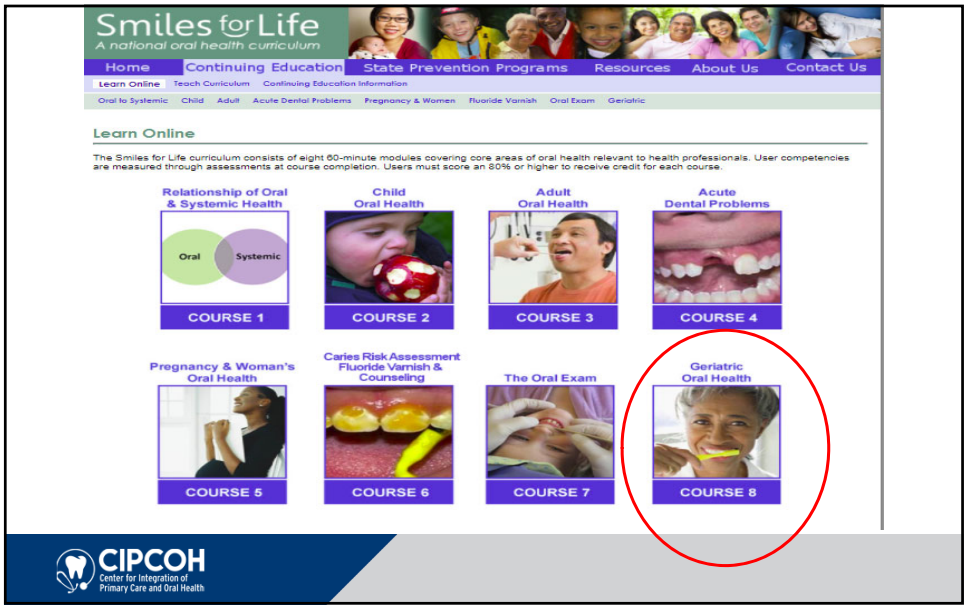

15

2nd Conclusion

- Addressing senior oral health will take more than a dental benefit in Medicare…look at Medicaid
- We need to use creative approaches to bring medical-dental together

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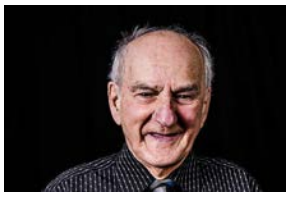
Last but not least…



- My patients stories
  - Edentulous - Marie
  - Pre/post dentures - Jim
  - Affect on nutrition, emotion, confidence…

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Thank You!

Hugh Silk, MD, MPH hughsilk@umassmed.edu

https://cipcoh.hsdm.harvard.edu

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18

1

Nurses as Oral Health Champions

- ✓Largest Health Profession
  - 3.8 million Registered Nurses (RNs)
  - 270,000 Nurse Practitioners (NPs)
    - 89% are certified in an area of primary care
  - 11,800 Nurse-Midwives (NMs)
- ✓Most Trusted Profession
  - Providing care and promoting health
- ✓Nurses are Everywhere
  - Hospitals, ambulatory centers, long-term care, acute care, workplace, retail clinics, homecare, primary care

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Nurse Practitioners as Key Interprofessional Team Members

- Primary Care Providers in LTC
- Common NH health issues may have oral etiology
  - Behaviors (mouth pain)
  - Decay/Tooth Loss
  - Weight loss
  - Nutritional deficits without weight change
    - B vitamins, D vitamins (change in cognition, anemia)
  - Oral infections→Systemic Infections

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Barrier to Oral Hygiene: Care-Resistant Behavior

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Knowledge that will change your world

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ARCORA

The Foundation of Delta Dental of Washington

Washington Dental Service Foundation

alzheimer's association

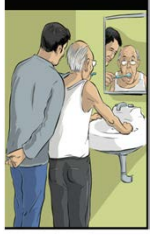
Community Advocates for Oral Health

Gestures

Caregiver note

When understanding verbal commands become too difficult, gestures and pantomime are valuable communication techniques that can prevent caregiver frustration and threat perception.

Mirror-mirror



Caregiver note:

Have the person with dementia stand in front of a mirror and the caregiver stand behind him or her to provide oral care.

Mirror-mirror is believed to be successful because it removes the caregiver from between the person and his or her image in the mirror.

The project described was supported in part by Award Number R01NR012737 from the National Institute of Nursing Research. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Nursing Research or the National Institutes of Health.

Developed by:

Washington Dental Service Foundation

Community Advocates for Oral Health

In partnership with:

alzheimer's association

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Oral Health for Caregivers

Caregivers, May 2018

Oral Health for Caregivers was developed by oral health experts and the Arcora Foundation. These online continuing education modules provide critical oral health information for those who care for older adults with an emphasis on prevention.

Designed for home care aides, the content, videos, and downloadable resources introduce oral health in an easy-to-understand format with strategies that can be implemented immediately.

Course Information

1. Oral Health Basics

- How oral health affects overall health
- How aging affects oral health
- Basic facts about oral health and ways to assist clients with routine oral care
- What a healthy mouth and unhealthy mouth look like
- How to identify and report unusual conditions in and around the mouth to help clients prevent oral disease or intervene early before a dental problem becomes serious

2. Improving Oral Health for Clients with Dementia

- How dementia effects the brain and behavior
- Understanding care-resistant behaviors (CRBs) of clients
- The relationship between oral health and dementia
- Practical strategies to overcome resistance to oral care

Cost: These training are offered FREE in Washington state. If you are located outside of Washington, please contact Karen Lewis at 206.528.7344.

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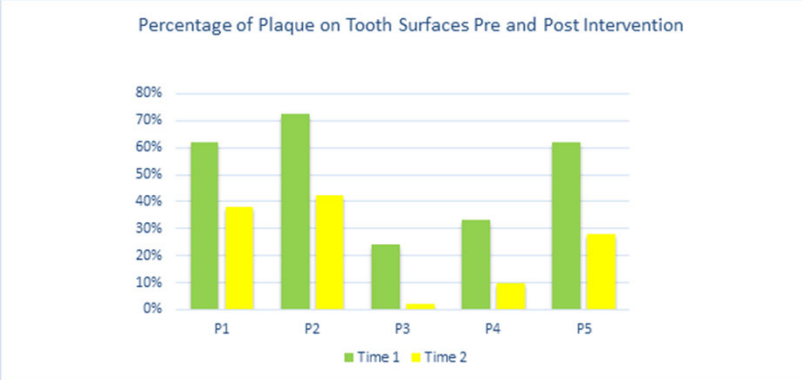
Effect of Once-Daily Brushing*



*Jablonski RA, Winstead V, Azuero A, Ptacek T, Jones-Townsend C, Byrd E, et al. Feasibility of Providing Safe Mouth Care and Collecting Oral and Fecal Microbiome Samples from Nursing Home Residents with Dysphagia: Proof of Concept Study. J Gerontol Nurs. 2017 Sep 1;43(9):9–15.

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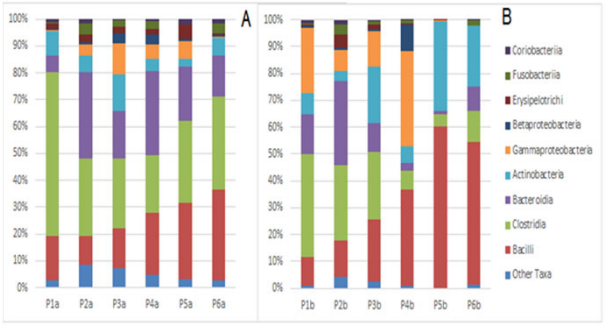
Effect of Once-Daily Brushing*

Bar Chart Depicting Supragingival Plaque Microbiota Composition by Subject, Before (A) and After (B) 4 Days of Once Daily Mouth Care



*Jablonski RA, Winstead V, Azuero A, Ptacek T, Jones-Townsend C, Byrd E, et al. Feasibility of Providing Safe Mouth Care and Collecting Oral and Fecal Microbiome Samples from Nursing Home Residents with Dysphagia: Proof of Concept Study. J Gerontol Nurs. 2017 Sep 1;43(9):9–15.

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"Brushing Away Infections"

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Impact of Dental Medicare Benefit

- 6 million people with dementia diagnosis
  - 1.6 million residents in "traditional" long-term care
  - 735k in assisted living facilities
- Current mouth care practices remove "soft plaque"
  - Need for dental benefit for scaling, subgingival plaque removal
  - Implications for improving gut microbiome, infection reductions

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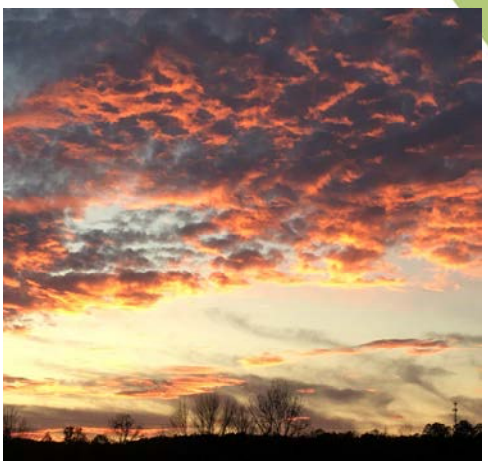
Nursing + Dentists + Dental Hygienists= Better Oral and Systemic Health Outcomes

- Nursing Profession as Leaders in LTCF
  - Nurse Practitioners
  - Licensed Nurses (RNs, LPNs)
    - Provide mouth care guidance, education to CNAs
- Medicare Benefit for Preventive Oral Health Services



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[Billing Code: 4120-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Ch. IV

[CMS-6082-NC]

RIN 0938-ZB54

Request for Information; Reducing Administrative Burden to put Patients over Paperwork

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS; Department of the Treasury

ACTION: Request for information.

SUMMARY: CMS is committed to transforming the health care delivery system--and the Medicare and Medicaid programs--by putting additional focus on patient-centered care, innovation, and outcomes. As part of our continuing Patients over Paperwork initiative, we have actively solicited feedback from the medical community through Requests for Information (RFIs), listening sessions, and clinical onsite engagements with front-line clinicians and staff to learn how our administrative requirements and processes affect their daily work and ability to innovate in care delivery. This RFI solicits additional public comment on ideas for regulatory, subregulatory, policy, practice, and procedural changes that reduce unnecessary administrative burdens for clinicians, providers, patients and their families. Through these efforts, we aim to increase quality of care, lower costs, improve program integrity, and make the health care system more effective, simple, and accessible.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on **[**Insert date 60 days after date of publication in the **Federal Register].**

ADDRESSES: In commenting, refer to file code CMS-6082-NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in **one** of the following three ways (please choose only **one** of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to **http://www.regulations.gov**. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-6082-NC,

P.O. Box 8016,

Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-6082-NC,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Morgan Taylor, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at (410) 786-3458.

Mary G. Greene, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at (410) 786-1244.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that Web site to view public comments.

I. Background

CMS is committed to transforming the health care delivery system--and the Medicare and Medicaid programs--by putting additional focus on patient-centered care, innovation, and outcomes. Our top priority is putting patients first and empowering them to make the best decisions for themselves and their families. Our continued goal is to eliminate overly burdensome and unnecessary regulations and subregulatory guidance in order to allow clinicians and providers to spend less time on paperwork and more time on their primary mission – improving their patients' health. We are also modernizing or eliminating outdated regulations to remove barriers to innovation. By reducing unnecessary paperwork, we are unleashing the most powerful force in our healthcare system for improving health outcomes: the clinician-patient relationship.

We launched our Patients over Paperwork initiative in 2017 to focus all of CMS on finding opportunities to modernize or eliminate rules and requirements that are outdated, duplicative, or getting in the way of good patient care. Public input has been critical to CMS achieving more flexibilities and efficiencies. As part of the Patients over Paperwork initiative, we actively solicited feedback from the medical community through requests for information (RFI), listening sessions, and clinical onsite engagements with front-line clinicians and staff to learn how our administrative requirements and processes affect their daily work and ability to innovate in care delivery. Through the RFI process alone, we received over 3,000 responses that outlined current burden and recommendations, which resulted in 1,146 distinct burden topics to address. Topics included, but were not limited to: Audits and Claims; Documentation Requirements; Health Information Technology; Interoperability; Provider Participation Requirements; Quality Measures and Reporting; Payment Policy and Coverage Determinations; the Physician Self-Referral Law; and Telehealth.

Over 2,000 clinicians, administrative staff and leaders, and beneficiaries have participated in our listening sessions and onsite engagements and we continue to send teams out into the field to learn more. This fieldwork helped elucidate how our rules affect workflow and decision-making, and potentially impede innovation. As of February 8, 2019, after reviewing and adjudicating all 1,146 burden topics with executive leadership across the agency, we have resolved or are actively addressing over 80 percent of the actionable RFI burden topics through changes to our regulations, subregulatory guidance, operations, or direct education and outreach to providers and beneficiaries. Please see the Appendix for a sample of what we have accomplished so far.

As we continue to work to maintain flexibility and efficiency throughout the Medicare and Medicaid programs, we would like to continue our national conversation about

improvements that can be made to the health care delivery system that reduce unnecessary burdens for clinicians, providers, and patients and their families. Through these efforts, we aim to increase quality of care, lower costs, improve program integrity, and make the health care system more effective, simple, and accessible. For these reasons, we are seeking comments on additional opportunities for improvement through this RFI.

II. Solicitation of Public Comments

We invite the public to submit ideas for regulatory, subregulatory, policy, practice, and procedural changes to better accomplish these goals. Specifically, we are soliciting new ideas not conveyed during our first RFI on this matter and innovative ideas that may help broaden perspectives about potential solutions. Ideas may include, but are not limited to:

- Modification or streamlining of reporting requirements, documentation requirements, or processes to monitor compliance to CMS rules and regulations;
- Aligning of Medicare, Medicaid and other payer coding, payment and documentation requirements, and processes;
- Enabling of operational flexibility, feedback mechanisms, and data sharing that would enhance patient care, support the clinician-patient relationship, and facilitate individual preferences; and
- New recommendations regarding when and how CMS issues regulations and policies and how CMS can simplify rules and policies for beneficiaries, clinicians, and providers.

We are particularly interested in recommendations on how CMS could:

- Improve the accessibility and presentation of CMS requirements for quality reporting, coverage, documentation, or prior-authorization;
- Address specific policies or requirements that are overly burdensome, not achievable, or cause unintended consequences in a rural setting;

- Clarify or simplify regulations or operations that pose challenges for beneficiaries dually enrolled in both Medicare and Medicaid and those who care for such beneficiaries; and
- Simplify beneficiary enrollment and eligibility determination across programs.

We are requesting respondents provide complete, clear, and concise comments that include, where practicable, data and specific examples.

III. Collection of Information Requirements

Please note, this is a request for information (RFI) only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

We note that this is a RFI only. This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, we are not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. We note that not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement

for additional information pertaining to this request. In addition, we note that CMS will not respond to questions about the policy issues raised in this RFI.

We will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. We may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders' written responses. Contractor support personnel may be used to review responses to this RFI. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. In addition, we may publically post the public comments received, or a summary of those public comments.

Dated: April 22, 2019.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: June 3, 2019.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.

Appendix: Patients over Paperwork Sample Accomplishments

The following is a sample of CMS accomplishments reducing unnecessary administrative burden in response to input from clinicians, providers, beneficiaries, and other stakeholders. For more Patients over Paperwork highlights, visit https://www.cms.gov/About-CMS/story-page/patients-over-paperwork.html.

Reducing Regulatory Burden

- Removed data elements from the Outcomes and Assessment Information Set (OASIS) assessment instrument.
- Removed the inpatient admission order documentation requirement in an effort to reduce duplicative documentation requirements at the time of admission.
- Removed the requirement that certification/recertification statements detail where in the medical record the required information can be found.
- Established the innovative new classification system, the Patient Driven Payment Model (PDPM), that ties skilled nursing facility payments to patients' conditions and care needs rather than volume of services provided, and simplifies complicated paperwork requirements for performing patient assessments by significantly reducing reporting burden.
- Eliminated the requirement that certifying physicians estimate how much longer skilled services are required when recertifying the need for continued home health care.
- Proposed giving facilities the flexibility to review their emergency program every 2 years, or more often at their own discretion, in order to best address their individual needs.
- Proposed allowing multi-hospital systems to have unified and integrated Quality Assessment and Performance Improvement (QAPI) and unified infection control programs for all of its member hospitals.

- Published a proposed rule to streamline Medicaid & CHIP managed care regulation.
- Issued Medicare Advantage (MA) and the prescription drug benefit program (Part D) final rule that promotes innovation, empowers patients and providers to make healthcare decisions, and includes burden-reducing provisions.

Simplifying Documentation Requirements

- Changed policy to allow a teaching physician to rely on medical student documentation and verify it rather than re-documenting the evaluation and management (E&M) service, and explained that the physician's signature and date is acceptable verification of the medical student's documentation.
- Provided an exception so that physicians acting as suppliers do not need to write orders to themselves.
- Simplified the requirements for preliminary/verbal Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) orders: Suppliers may dispense most items of DMEPOS based on a verbal order or preliminary written order from the treating physician.
- Clarified DMEPOS written order prior to delivery date requirements: If the written order is dated the day of or prior to delivery, there is no need for affirmative documentation of it being "received".
- Clarified that a supplier can use the discharge date as the date of service if mailing 1 or 2 days before discharge.
- Released a newly revised Skilled Nursing Facility Advanced Beneficiary Notice (SNFABN) with concise instructions and no longer using the 5 denial letters and Notice of Exclusion from Medicare Benefits – SNF.

Focusing on Meaningful Measures

- Our Meaningful Measures initiative is centered on holding providers accountable for patient health outcomes, safe and efficient care, and making sure the measure sets providers are asked to report on are meaningful to patients and clinicians alike.

- Reduced the burden of reporting quality measures in MIPS with a focus on reporting through electronic means and incentivizing the use of clinical registries.

Improving Operational Efficiencies and Interoperability

- In implementing the Quality Payment Program (QPP), established a consolidated data submission experience for the different performance categories of the Merit-based Incentive Payment System (MIPS) so that clinicians no longer need to submit data in multiple systems as under the legacy programs (the Physician Quality Reporting System (PQRS) and the Medicare Electronic Health Record (EHR) Incentive Program).

- Refocused the Medicare EHR Incentive Program (now called the Promoting Interoperability Program) on interoperability, emphasizing exchange of health information between patients and providers.

- Implemented changes resulting in faster processing of state requests to make program or benefit changes to their Medicaid program through the state plan amendment (SPA) and section 1915 waiver review process.

Enhancing Transparency and Consistency

Made significant changes to the Medicare Program Integrity Manual Chapter 13 to improve transparency in the Local Coverage Determination process. The manual includes instructions, policies and procedures for Medicare Administrative Contractors (MAC) that administer the Medicare program in different regions of the country, as well as guidance for stakeholder engagement in the process.

Offering Burden-Reducing Flexibilities in Payment Model Demonstrations

- In the Bundled Payments for Care Improvement Advanced (BPCI Advanced) model, CMS issued the Post-Discharge Home Visit Payment Policy waiver which allows for certain services to be delivered in the eligible model beneficiary's home by auxiliary personnel under the general supervision of a participating practitioner.

- In the Next Generation Accountable Care Organization (Next Gen ACO) model, CMS issued the Telehealth Expansion waiver which allows for eligible model beneficiaries to receive Telehealth services in their home.

[FR Doc. 2019-12215 Filed: 6/6/2019 11:15 am; Publication Date: 6/11/2019]

May 13, 2019

The Honorable Frank Pallone
Chairman
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Greg Walden
Ranking Member
House Committee on Energy and Commerce
2322-A Rayburn House Office Building
Washington, DC 20515

The Honorable Richard Neal
Chairman
House Committee on Ways and Means
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Kevin Brady
Ranking Member
House Committee on Ways and Means
1139 Longworth House Office Building
Washington, DC 20515

Dear Chairmen Pallone and Neal and Ranking Members Walden and Brady,

The undersigned are writing to express our strong support for the reauthorization of the Patient-Centered Outcomes Research Institute (PCORI). Our health care system requires solutions that are both evidence-based and patient-centered, to improve care while also addressing health care spending. PCORI is uniquely set up to meet this challenge, as it is the only organization dedicated to funding comparative clinical effectiveness research (CER) studies comparing which treatment approaches work best, for which patients, given their needs and preferences. The goal is to help health care providers and payers better understand health care treatment options and to help patients and those who care for them make better informed health and health care decisions. Delivering care that is most clinically effective and incorporates outcomes that matter to patients is both cost effective and essential to our well-being as a nation.

As of December 2018, PCORI has awarded more than $2.4 billion in grants to more than 600 research-related projects in 44 states across the U.S. In 2014, PCORI saw the first large number of research results from its funded studies reported in major medical journals. Several of these projects generated particularly promising evidence for improving care and patient outcomes in key areas, such as cardiovascular disease, prostate cancer, opioid prescribing, and type 2 diabetes management.

PCORI-funded research also supports personalized care by discouraging ineffective and low-value care. In fact, the U.S. Government Accountability Office concluded in its March 2018 report that PCORI is fulfilling its Congressional mandate to develop and promote the application of solid methodology standards for conducting trustworthy CER.

Unless Congress acts, however, all of this work will cease at the end of September 2019. To build on the momentum to date and to enable PCORI to continue its work toward achieving smarter and more efficient health care spending, we ask you to consider the following recommendations.

Reauthorize PCORI and its current funding mechanism for at least an additional 10 years.
Among PCORI's signature achievements in its first 10 years has been the creation of a new paradigm for conducting research that better integrates patient perspectives. PCORI uniquely funds patient-centered outcomes research that engages patients throughout the research process, including in the research design, so that it captures outcomes that matter to patients to improve health care decisions. This is a vitally important function, and PCORI research provides a wealth of valuable data for patients and health care providers, while also informing how the health care system can be more efficient. Research is a long-term endeavor, and some high quality CER studies can take 4-5 years to complete. Even after the completion of these studies, additional time is needed to develop and implement clinical decision support and shared decision-making tools.

For the ongoing investment in PCORI-funded research to be most impactful, stability in PCORI funding is imperative to allow ample time to conclude studies, disseminate the findings, develop implementation tools, and drive implementation where appropriate. Reaffirming the commitment to PCORI for another 10 years will allow the institute to build on its success in changing the culture of research to be more patient-centered, and to enhance its work in partnership with other agencies and stakeholders to support a sustainable infrastructure for disseminating and implementing research outcomes meaningfully into practice.

Ensure PCORI stays true to its mission of patient-centered research by maintaining its mandate to conduct comparative clinical effectiveness research.
All stakeholders agree that high-quality, evidence-based care is crucial to reducing costs in the health care system. PCORI is the only research organization dedicated to funding studies that compare care approaches to determine what works best, for whom, and under which circumstances. By providing feedback on what care is going to provide the best result to each patient, PCORI is generating invaluable information that will save our health care system significant expenditures by empowering patients to choose treatments that work best and therefore limit adverse events such as hospitalization and multiple courses of treatment.

In creating PCORI, Congress committed to build the evidence base for improved health decisions, seeking to empower patients and drive innovation and value in health care. Reauthorization is an opportunity for Congress to ensure that PCORI continues to uphold this commitment and serve the needs of an evolving health care system.

We look forward to engaging with you throughout the reauthorization process. Thank you for your consideration of our recommendations.

Sincerely,

Organizations
Academy of Managed Care Pharmacy
AcademyHealth
AfricanAmericansAgainstAlzheimer's Network
Alliance for Aging Research
American Academy of Family Physicians
American Academy of Neurology
American Academy of Pediatrics
American Association for Dental Research

American Association for Respiratory Care
American Association for the Study of Liver Diseases
American Association of Colleges of Pharmacy
American Association of Neurological Surgeons and Congress of Neurological Surgeons
American Association of Orthopaedic Surgeons
American Association on Health and Disability
American Chiropractic Association
American College of Physicians
American College of Surgeons
America's Essential Hospitals
American Heart Association
American Liver Foundation
American Lung Association
American Medical Informatics Association
American Multiple Endocrine Neoplasia Support
American Parkinson Disease Association
American Psychological Association
American Society for Transplantation and Cellular Therapy
American Society of Hematology
American Society of Nephrology
American Thoracic Society
American Urological Association
Arthritis Foundation
Associated Medical Schools of New York
Association for Clinical and Translational Science
Association for Community Affiliated Plans
Association of American Medical Colleges
Association of American Universities
Association of Departments of Family Medicine
Association of Family Medicine Residency Directors
Association of Pathology Chairs
Association of Public and Land-grant Universities
Association of Rehabilitation Nurses
Association of Schools and Programs of Public Health
Association of University Centers on Disabilities
Asthma and Allergy Foundation of America
Better Medicare Alliance
Brain Injury Association of America
BrightFocus Foundation
Caregiver Action Network
Cedars-Sinai
Celiac Disease Foundation
Children's Hospital of Philadelphia
Cholangiocarcinoma Foundation
Cincinnati Children's Hospital Medical Center
Clinical Research Forum
Coalition for Clinical and Translational Science
Coalition for Disability Health Equity

Coalition to Transform Advanced Care (C-TAC)
Columbia University Irving Medical Center
COPD Foundation
Creighton University School of Medicine
Crohn's & Colitis Foundation
Cure HHT
Dartmouth Hitchcock Health
Davis Phinney Foundation
Digestive Disease National Coalition
Dorney-Koppel Foundation
Duke University School of Medicine
Dystonia Advocacy Network
Dystonia Medical Research Foundation
Epilepsy Association of North Carolina
Epilepsy Foundation
Families USA
FasterCures
Fight Colorectal Cancer
Friends of Cancer Research
GBS|CIDP Foundation International
Genetic Alliance
Global Healthy Living Foundation
Global Liver Institute
Go2Foundation for Lung Cancer
Harvard Medical School
Healthcare Leadership Council
Healthcare Research Associates LLC/ The S.T.A.R. Initiative
Heart Valve Voice US
Hydrocephalus Association
ICAN, International Cancer Advocacy Network
Indiana University
Infectious Diseases Society of America
International Foundation for Gastrointestinal Disorders
International Pemphigus and Pemphigoid Foundation
Interstitial Cystitis Association
Johns Hopkins University & Medicine
Lakeshore Foundation
LatinosAgainstAlzheimer's Network
Louisiana Public Health Institute
Lupus and Allied Diseases Association Inc.
Lymphatic Education & Research Network
Mended Hearts
Men's Health Network
METAvivor
Muslims for Evidence Based Healthcare
National Alliance on Mental Illness
National Alopecia Areata Foundation
National Ataxia Foundation

National Blood Clot Alliance
National Fibromyalgia and Chronic Pain Association
National Health Council
National Hispanic Medical Association
National Kidney Foundation
National Multiple Sclerosis Society
National Organization for Rare Disorders (NORD)
National Pancreas Foundation
National Partnership for Women & Families
National Psoriasis Foundation
NEC Society
Nemours Children's Health System
NephCure Kidney International
Neuropathy Action Foundation
NHMH - No Health without Mental Health
North American Primary Care Research Group
NYU School of Medicine
Ochsner Health System
Parkinson's Foundation
Partners Healthcare
Partnership to Improve Patient Care
Patient-Centered Primary Care Collaborative
Phelan-McDermid Syndrome Foundation
Planetree International
Powerful Patient Inc.
Prisma Health
Project Sleep
Public Sector HealthCare Roundtable
Pulmonary Fibrosis Foundation
Pulmonary Hypertension Association
PXE International
Research!America
Restless Legs Syndrome Foundation
Scleroderma Foundation
Sleep Research Society
Society of General Internal Medicine
Society of Teachers of Family Medicine
Stanford University School of Medicine
Sterling Health IT
Sturge-Weber Foundation
The Marfan Foundaton
The Michael J. Fox Foundation for Parkinson's Research
The Robert Larner MD College of Medicine at The University of Vermont
The Society of Thoracic Surgeons
Tulane University School of Medicine
UC San Francisco (UCSF)
University Hospitals, Cleveland, Ohio
University of Alabama at Birmingham

University of California System
University of Colorado Anschutz Medical Campus
University of Florida
University of Hawaii John A. Burns School of Medicine
University of Kansas Medical Center
University of Maryland, Baltimore
University of New Mexico Health Sciences Center
University of Pennsylvania Health System (Penn Medicine)
University of Pittsburgh
University of Virginia Health System
USCOPD Coalition
US Hereditary Angioedema Association
UW Medicine
Vanderbilt University Medical Center
Virginia Commonwealth University
Wake Forest School of Medicine
Washington University, St. Louis
Weill Cornell Medicine

PCORI Ambassadors
Bill Adams, PCORI Ambassador, Erhard, Minnesota
Peter Anderson, PCORI Ambassador, Charleston, West Virginia
Sonya Ballentine, PCORI Ambassador Chicago Health Disparities Center, Illinois
Rosie Bartel, Patient Advocate, Chilton, Wisconsin
James Beck, MD, Vice Dean for Government Affairs and Health Care Policy, Marshall University Joan C. Edwards School of Medicine, Huntington, West Virginia
Jennifer Canvasser, PCORI Ambassador, Davis, California
Martie Carnie, PCORI Ambassador, Senior Patient Experience Advisor, Center for Patients and Families, Brigham and Women's Hospital, Boston, Massachusetts
Thomas Carton, Chief Data Officer, Principal Investigator, Louisiana Public Health Institute
Matt Cheung, PCORI Ambassador, Los Gatos, California
Kimerly Coshow, PhD, PCORI Ambassador, Parkinson's Disease Patient & Research Advocate, Blue Ridge, Georgia
Maureen Fagan, PCORI Patient Experience Panelist and Chief Experience Officer, University of Miami Health System
Venus Gines, President & Founder, Dia de la Mujer Latina, Manvel, Texas
Lawrence Goldberg MD, PCORI Ambassador, Philadelphia, Pennsylvania
Regina Greer- Smith, PCORI Ambassador, Illinois
Heather Guidone, PCORI Ambassador, Atlanta, Georgia
James Harrison, PCORI Ambassador, Assistant Professor, University of California, San Francisco
Jill Harrison, Director of Research, Planetree International, Derby, Connecticut
Marcia Horn, PCORI Ambassador, Phoenix, Arizona
Matthew Hudson, Ph.D., M.P.H, Director of Cancer Care Delivery Research, Greenville, South Carolina
Wenora Johnson, PCORI Ambassador, Illinois
Leslie MacGregor Levine PhD, VMD, JD, PCORI Ambassador, advisory panel member and merit reviewer, patient advocate, Neuropathy Action Foundation, Boston, Massachusetts
Susan Lin, PCORI Ambassador, Advisory Panel member, and Merit Reviewer, Round Hill, Virginia

Donald A. McClain, Senior Associate Dean for Clinical Research Director, Clinical and Translational Science Institute, Wake Forest School of Medicine
Seth Morrison, PCORI Patient Reviewer and patient advocate, Las Vegas, Nevada
James Pantelas, PCORI Ambassador, Howell, Michigan
Maria Pellerano, PCORI Ambassador, New Brunswick, New Jersey
Philip Posner, PCORI Ambassador, Arlington, Virginia
Joan D. Powell, MDS Patient Advocate, Laguna Niguel, California
Ting Pun, PCORI Ambassador and Stanford Healthcare PFAC, Portola Valley, California
Bobbie Reed, PCORI Ambassador, Wexford, Pennsylvania
Anita Roach, M.S., PCORI Ambassador, Arlington, Virginia
Brendaly Rodriguez, MA, CPH, University of Miami Miller School of Medicine
Beverly Rogers, PCORI Ambassador, Indianapolis, Indiana
Carol Schulte, PCORI Ambassador, Red Bank, New Jersey
Norah Schwartz, Ph.D., PCORI Ambassador, San Diego, California
Sandra Sufian, Associate Professor; University of Illinois, College of Medicine and Applied Health Science
Jeff Taylor, PCORI Ambassador, Palm Springs, California
Rachelle Tepel PhD, PCORI Ambassador, Arlington, Virginia
Beverly Watkins, PCORI Ambassador, New York, New York
David White, PCORI Ambassador and Chair, Advisory Committee on Patient Engagement, Prince George's County, Maryland
Freddie White-Johnson, President & CEO, Fannie Lou Hamer Cancer Foundation Director, Mississippi Network for Cancer Control and Prevention
Ron Wincek, PCORI Ambassador, Atlanta, Georgia

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Research Funding

The Patient-Centered Outcomes Research Institute (PCORI) is a nonprofit organization authorized by Congress to fund comparative clinical effectiveness research, or CER. The studies we fund are designed to produce reliable, useful information that will help patients, family caregivers, clinicians, employers, insurers, policy makers and others make better-informed health and healthcare decisions. Our work is guided by a 21-member Board of Governors representing the entire healthcare community.

MORE THAN
$2.4B
AWARDED

MORE THAN
600
RESEARCH-RELATED PROJECTS

CER AND PCOR

CER is research that compares two or more available healthcare options to determine what works best for which patients, under what circumstances. PCORI supports patient-centered outcomes research, or PCOR, which is CER that focuses not only on traditional clinical outcomes but also on the needs, preferences, and outcomes most important to patients and those who care for them.

KEY FEATURES OF OUR FUNDED RESEARCH

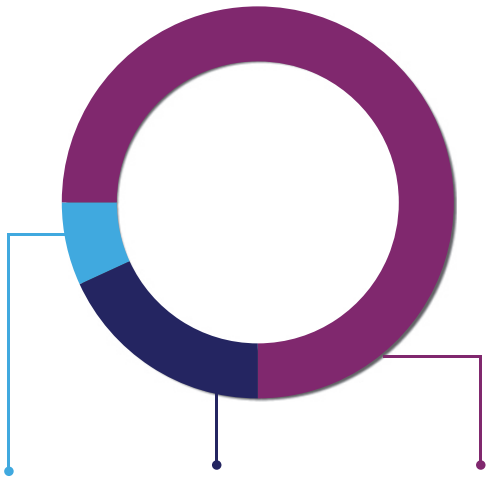
- Compares at least two alternative healthcare options
- Focuses on outcomes that are meaningful to patients
- Engages patients and other stakeholders at every stage
- Studies benefits and harms of care delivered in real-world settings
- Adheres to PCORI's Methodology Standards
- Is likely to improve current clinical practice

WE PAY PARTICULAR ATTENTION TO:

- Conditions that heavily burden patients, families, and/or the healthcare system
- Chronic or multiple conditions
- Rare and understudied conditions
- Conditions with varied outcomes across subpopulations

BY THE NUMBERS

Research Projects By Area



METHODOLOGY
$136 Million (6%)

INFRASTRUCTURE
(Including PCORnet)
$377 Million (16%)

CER
$2 Billion (78%)

Most Studied Conditions*

Mental/Behavioral Health	121
Cancer	86
Neurological Disorders	74
Cardiovascular Diseases	69
Multiple/Comorbid Chronic Conditions	58

Most Studied Priority Populations*

Racial/Ethnic Minorities	301
Low Socioeconomic Status	200
Women	154
Older Adults	137
Individuals with Multiple Chronic Conditions	112

**Number of projects (out of a total of 455). A project may study more than one condition or priority population.*

ENGAGEMENT

We believe research that involves patients and other stakeholders from the start will lead to useful results more likely to be taken up in practice. So we engage patients and other stakeholders in all aspects of our work and require the research projects we fund to do so as well.

RESEARCH PRIORITIES

Our research funding is guided by five National Priorities for Research, which we developed with significant input from across the healthcare community. These are:

- **Assessment of Prevention, Diagnosis, and Treatment Options**
- **Improving Healthcare Systems**
- **Addressing Disparities**
- **Communication and Dissemination Research**
- **Accelerating Patient-Centered Outcomes Research and Methodological Research**

INPUT FROM PATIENTS AND OTHER STAKEHOLDERS

Our funding decisions are guided by input from all sectors of the healthcare community.

- We solicit potential research topics and questions from the community.
- We prioritize topics that meet critical needs through our multi-stakeholder PCORI Advisory Panels.
- We engage patients and other stakeholders in reviewing applications for our funding.

We issue calls for research proposals through PCORI Funding Announcements, which can be found on our website at *www.pcori.org/funding-opportunities*. Types of announcements:

- Calls for CER studies related to our five National Priorities for Research
- Calls for proposals on specific topics prioritized by stakeholder input
- Calls for proposals for pragmatic clinical studies addressing specific prioritized topics

METHODS MATTER

Better methods will produce more valid, useful information that will lead to better healthcare decisions and, ultimately, to improved patient care and outcomes. To that end, we fund research on ways to improve the conduct of PCOR. And per our authorizing legislation, we've developed a set of Methodology Standards as the basis for sound PCOR.

BUILDING CAPACITY FOR MORE EFFICIENT RESEARCH

PCORnet, a PCORI-funded initiative, enables patient-centered clinical research to be conducted faster, more easily and more efficiently. It does so by tapping into rich sources of real-world data collected during routine care through electronic health records, patient-reported outcomes, health claims and other sources.

pcornet®
The National Patient-Centered Clinical Research Network

By leveraging this information, PCORnet generates real-world evidence about the comparative clinical effectiveness of therapies, diagnostics, and prevention strategies.

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE: **A PRIMER FOR 2019**

WHY THE NATION NEEDS PCORI

Patients and their doctors make choices about health care every day, but often lack the evidence to choose care that best meets the patient's needs. That can mean greater burdens on individuals, families, and the health care system. That's why the **Patient-Centered Outcomes Research Institute (PCORI)** was authorized by Congress in 2010 as a private, nonprofit research funder that would address this need.

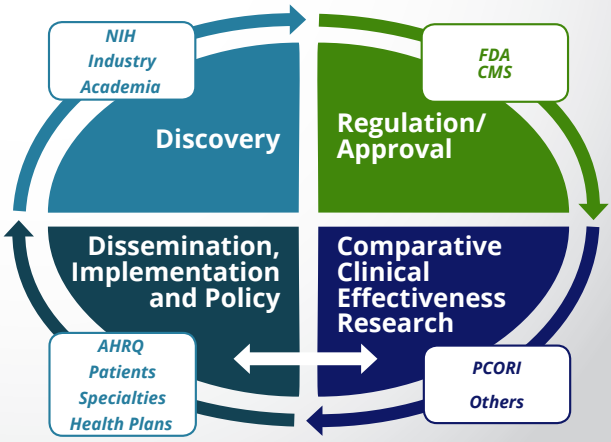
PCORI does this by funding patient-centered outcomes research (PCOR)—studies that determine how well different tests and treatments work compared to others, given the health outcomes patients care about. This research gives patients and their doctors information they need to choose the most effective treatment options available to them.

PCORI-funded research has real impacts related to pressing health problems, including heart disease, diabetes, opioid addiction, mental health, and cancer. It produces evidence that helps our health care system to deliver high quality, effective care; reduce disparities; and use resources most efficiently to produce better patient outcomes.

PCORI'S UNIQUE ROLE

"Patient centered" is the guiding principle that drives PCORI's work. It engages patients and their caregivers, alongside clinicians and payers, throughout the research process, from reviewing proposals to helping guide studies and disseminate findings. In addition, PCORI is our country's only research funder exclusively dedicated to understanding how available treatments and medications compare. While other funders focus on discovery and developing new treatments, PCORI's research gives us the information we need to make decisions about which available treatments work best based on individual circumstances, preferences, and values.

PCORI IN THE RESEARCH ECOSYSTEM



PRIORITY TOPICS


Cancer


Cardiovascular Diseases


Mental and Behavioral Health


Multiple/Comorbid Chronic Conditions


Neurological Diseases

PRIORITY POPULATIONS


Low Socioeconomic Status

Older Adults


People with Multiple/Comorbid Chronic Conditions


Racial/Ethnic Minorities


Women

EXAMPLES OF PCORI'S IMPACT

Addressing Chronic Pain and Opioid Use

- A PCORI-funded study found that alternative therapies for opioid-treated chronic lower back pain give patients more control over pain management and lower their risk of addiction.

Managing Type 2 Diabetes

- Another study found that people with type 2 diabetes who aren't insulin dependent could choose to forego daily finger-prick tests, which could improve their quality of life and lower health care costs.

Chest Pain and Hospitalizations

- Using a simple decision aid can help many patients with chest pain safely avoid unnecessary hospitalizations for follow-up testing. That can mean significant savings.

Antibiotics for Children

- Results showed that treating children hospitalized for serious infections with oral instead of intravenous antibiotics prevented recurrence of infections, and was as safe and less burdensome for children and their families.

FUNDING

PCORI has committed **$2.4 billion** to research and related projects. These include studies comparing two or more treatments or care approaches to see which works better for whom. PCORI also has invested in advancing the research methods and infrastructure needed to support rigorous, patient-centered research.

Authorization for the Patient-Centered Outcomes Research Trust Fund expires on September 30, 2019. Congress must act to ensure continued support for this critical research helping patients and providers make evidence-based health care decisions that work best for them.

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Highlights of PCORI-Funded Research Results

Since PCORI began funding research in 2012, a growing number of our funded studies have produced important results that are being reported in leading medical journals. Here are examples:

For Many with Type 2 Diabetes, Daily Finger Sticks Offer Little Health Benefit

People with type 2 diabetes who are not using insulin are often advised to check their blood sugar levels using daily finger sticks, which can be painful and inconvenient, as well as run up out-of-pocket costs for test strips. This study suggests that for these patients, daily self-monitoring does not help control diabetes or delay the need to start insulin compared with not doing so.

Over five years,
10 BILLION
finger sticks could be avoided

Young L et al. *JAMA Intern Med*. 2017 Jul 1; 177(7)

Initiative to Reduce Risky Opioid Prescribing Works

This study compared rates of opioid use in clinics in Washington State that implemented an initiative focused on more-cautious prescribing of opioid drugs with clinics that did not use such strategies. This health system-based initiative led to reductions in high-dose opioid prescribing, and patients did not report worse pain control.

Von Korff M et al. *J Pain*. 2016 Jan; 17(1)

Engaging Parents in Hospital Rounds to Ensure Patient Safety

Improving communication among patients and staff in the hospital can help reduce harmful medical errors, a leading cause of death. A PCORI-funded research team found that using a program called I-PASS, which includes parents as active participants in clinicians' rounds of pediatric units, reduced preventable adverse events by 38 percent.

Landrigan C et al. *BMJ*. 2018 Dec 5; 363:k4764

Bypass Shown to Be Most Effective Weight-Loss Surgery Procedure

This study, the largest to date to compare weight-loss surgeries, analyzed 46,000 patients' outcomes using PCORnet. Adults who had Roux-en-Y gastric bypass, a long used approach, lost more weight and kept it off better than those who had the newest procedure, sleeve gastrectomy. Both bypass and sleeve were more effective than adjustable gastric banding. Risks of major adverse events shortly after surgery were small for all three surgeries, but were highest for bypass.

Arterburn D et al. *Ann Intern Med.* 2018 Oct 30;169(9)

Simple Questionnaire Enhances Shared Decision Making about Chest Pain

A questionnaire called Chest Pain Choice can help people who go to the emergency department with chest pain, but who are found to not be having a heart attack, decide whether to be admitted to the hospital for follow-up tests or go home and have the tests later. People who used the aid were much more likely to go home from the emergency department, with no increase in later heart-related problems.

Over five years,
9.4 MILLION
Americans could benefit from using the decision aid

Hess E et al. *BMJ*. 2016 Dec 5; 355

For Earaches and Strep Throat in Kids, Narrow-Spectrum Antibiotics Are Better

Narrow-spectrum antibiotics did just as well for clearing up ear infections and sore throats caused by bacteria as more-expensive broad-spectrum antibiotics did. Broad-spectrum drugs caused more side effects, such as vomiting. Unnecessary use of broad-spectrum antibiotics is associated with increasing bacterial drug resistance.

Gerber JS et al. *JAMA*. 2017 Dec 19;318(23)

Oral Antibiotics Work as Well as IV, with Fewer Costly Complications

In preventing a recurrence of infection, children discharged from the hospital after a serious bacterial infection did just as well on oral antibiotics as those sent home with an IV line to deliver antibiotics intravenously. They also had none of the frequent complications IV lines can cause.

Keren R et al. *JAMA Pediatr*. 2015 Feb; 169(2)
Shah S et al. *Pediatrics*. 2016 Dec; 138(6)
Rangel S et al. *Ann Surg*. 2017 Aug; 266(2)

Disadvantaged Patients with Chronic Pain Benefit from Tailored Nondrug Therapies

Chronic pain occurs more frequently in people with lower education and income levels. In this study, both cognitive behavioral therapy and pain educational material, each tailored to match patients' education levels, significantly lessened pain and improved physical function compared with usual care. These nondrug approaches can help manage chronic pain and reduce the need for opioids. These findings show such approaches can be effective in patients with low incomes and limited reading skills.

Thorn B et al. *Ann Intern Med*. 2018 Apr 3;168(7)

Findings Help Men Choose among Prostate Cancer Treatment Options

Two PCORI-funded studies provided men with up-to-date information about the rates of several major side effects associated with current treatments for prostate cancer. The information applies to robot-assisted surgery and newer forms of radiation therapy, as well as active monitoring instead of immediate treatment. These results will help men with prostate cancer and their families better weigh the benefits and risks of each treatment in consultation with their clinicians.

Barocas D et al. *JAMA*. 2017 Mar 21; 317(11)
Chen R et al. *JAMA*. 2017 Mar 21; 317(11)

For Earaches and Strep Throat in Kids, Narrow-Spectrum Antibiotics Are Better

Narrow-spectrum antibiotics did just as well for clearing up ear infections and sore throats caused by bacteria as more-expensive broad-spectrum antibiotics did. Broad-spectrum drugs caused more side effects, such as vomiting. Unnecessary use of broad-spectrum antibiotics is associated with increasing bacterial drug resistance.

Gerber JS et al. *JAMA*. 2017 Dec 19;318(23)

Blood Thinner Keeps Stroke Survivors in Their Homes

Over five years in the United States,
466
strokes could be avoided

Using the blood thinner warfarin helped stroke survivors reduce future hospitalizations and stay in their homes—on average 46 more days at home over two years—compared with those who didn't take the drug after being discharged from the hospital. The drug also lowered the rates of stroke recurrence and heart attack, but staying at home rather than having to go to a nursing home or hospital was the outcome that mattered most to patients.

Xian Y et al. *BMJ*. 2015; 351
O'Brien EC et al. *Circulation*. 2015 Oct 13; 132 (15)

Shared Decision Making Helps Decisions Related to Advanced Heart Failure

Surgically implanting a left ventricular assist device (LVAD) can prolong the lives of people with end-stage heart failure. But the surgery and device carry significant risk for harms, such as infections and stroke. Using a shared decision making tool improved patients' knowledge about the potential benefits and risks of an LVAD compared with typical educational pamphlets. The aid also helped them make initial decisions better aligned with their values.

Allen LA et al. *JAMA Intern Med*. 2018 Apr 1; 178(4)

Behavioral Health Homes Improve Outcomes for People with Mental Illness

Behavioral health homes, a patient-centered way of coordinating care for patients with both mental and physical health needs, can help people with serious mental illnesses manage their conditions and possibly live longer, healthier lives. Two ways of providing a behavioral health home—a patient self-directed approach and a healthcare provider-supported approach—both significantly increased patients' knowledge and confidence to manage their own care and increased their engagement in care, but the provider-supported approach did so faster.

Schuster J et al. *Health Aff*. 2018 Feb; 37(2)

For additional highlights of PCORI-funded research results, visit our website at www.pcori.org/results.

And to explore all results from PCORI-funded studies to date, visit www.pcori.org/completed-projects.

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Research Done Differently®

THE PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE (PCORI) TAKES AN UNUSUAL APPROACH TO RESEARCH, ONE THAT

Focuses on research topics, questions and **outcomes most important to patients** and those who care for them.

Works closely with a **range of healthcare stakeholders**—including patients, caregivers, scientists, clinicians, health systems, and insurers—to guide our research funding.

Requires that **patients be engaged** in the research we fund, not as subjects but as partners who help determine what to study and how.

THIS NEW APPROACH IS CALLED **PATIENT-CENTERED OUTCOMES RESEARCH, OR PCOR.**

By engaging the end users of study results throughout the research process, we are more likely to focus on asking the right questions, study the outcomes that matter most to patients, and produce the useful and relevant results that are more likely to be used in practice.

Changing the Culture of Research

Since we began funding research in 2012, our approach to research has fueled a rapid increase in patient-centered research and collaborations among patients, family caregivers, clinicians, researchers, health system leaders, and other healthcare stakeholders. In the process, we're spurring a change in the culture of research from being researcher-driven to stakeholder-driven.

We believe that PCORI's leadership in patient and stakeholder engagement is one of the key reasons this trend is accelerating throughout the research and health policy arenas. In just the past few years:

- Institutions such as Geisinger Health System have been revamping their research processes to include patients and enhance engagement.
- The US Food and Drug Administration announced its first patient engagement advisory committee in 2015.
- The National Institutes of Health has welcomed robust involvement of patients in the Precision Medicine Initiative.

"It's difficult to imagine research without engaging patients and caregivers and other stakeholders anymore. That's a cultural shift that PCORI's responsible for."

—Victor Montori, MD
Professor of Medicine
Mayo Clinic

"As part of the reexamination of our strategic plan, we formed a working group to explore patient engagement in research and to answer the question of how we could best take advantage of the opportunities that working with PCORI offered us."

—Marc S. Williams, MD
Director
Genomic Medicine Institute,
Geisinger Health System

"[PCORI has] made it very clear that we are partners in this. It isn't that they're the researchers and we're just the parents. [It's] that we're equals in this."

—Andrea Jensen,
Patient Caregiver

As of December 2018, PCORI has awarded

$2.4 BILLION TO FUND MORE THAN 600

CER studies and related projects to enhance the methods and infrastructure to support PCOR.

PCORI funds **patient-centered comparative clinical effectiveness research, or CER**. This is research that aims to determine which healthcare options work best for which patients given their needs and preferences. The goal is to help patients and those who care for them to make better informed health and healthcare decisions.

By **patient-centered**, we mean that the studies we fund focus on outcomes that matter most to patients. We are also leading efforts to engage patients, family caregivers, clinicians, and other healthcare stakeholders as active partners in research, helping research teams decide what to study and how to study it.

> *"My interactions with PCORI have completely changed my approach to research. In fact, they inspired me to establish a center for patient-centered comparative clinical effectiveness research."*
>
> **—Debra Fiser, MD**
> **Professor and Former Dean**
> **College of Medicine, University of Arkansas for Medical Sciences**

> *"This PCORI-funded project has truly taught me about the benefits of conducting research in partnership with patients, caregivers, and advocates. I will never again be able to conceptualize or implement a research project without the input of these important stakeholders."*
>
> **—Supriya Mohile, MD, MS**
> **Professor of Medicine**
> **University of Rochester**

pcornet®
The National Patient-Centered Clinical Research Network

Our research funding includes **$1.54 billion** to support patient-centered studies comparing two or more healthcare options, and another **$124 million** for research to improve the science and methods of CER.

We've Invested $325 million to develop PCORnet®, the National Patient-Centered Clinical Research Network, a **resource for conducting faster, more-efficient health research** by harnessing data representing 100 million patients and partnerships among hundreds of patients, clinicians, and healthcare organizations.

In addition to our research funding, we've provided another $58 million to support projects and activities to stimulate partnerships, grow communities engaged in PCOR, and nurture ideas for PCOR into study proposals.

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

1828 L STREET NW, SUITE 900
WASHINGTON, DC 20036
202.827.7700

POTENTIAL IMPACT OF PCORI-FUNDED STUDY RESULTS

Self-Monitoring of Blood Glucose for People with Type 2 Diabetes Who Don't Use Insulin

WHAT'S THE ISSUE?

Many people with type 2 diabetes who are not on insulin use diet, exercise, and medicine to manage their blood sugar levels. They may also use daily finger sticks to measure their blood sugar levels with personal monitors. But such daily monitoring can be inconvenient and painful, supplies can be costly, and the health benefits have been unclear.

WHAT DID THE PCORI-FUNDED STUDY FIND?

A PCORI-funded study found no significant differences after one year in hemoglobin A1c, a measure of blood sugar control, or in health-related quality of life between patients who did and did not test their blood sugar daily.

GAUGING THE POTENTIAL IMPACT OF THE RESULTS

Our simulation model looked at the potential national effect on the amount of testing and on healthcare costs if patients with type 2 diabetes who are not taking insulin stopped testing their blood sugar daily. The model used U.S Centers for Disease Control and Prevention estimates of a population of 7.1 million people aged 30 and older in the United States who perform an average of 5.4 self-tests per week.

POTENTIAL CHANGES IN TESTING AND COSTS

Over five years, if all eligible patients stopped testing their blood sugar daily, the result could be 10 billion fewer blood glucose tests—and finger sticks. Test strips cost an average of $325 per person per year in this population. So, avoiding daily testing could save $2.3 billion per year, or $11.6 billion over 5 years.

R E S U L T

The study found **no significant differences** after one year in hemoglobin A1c levels between patients who did and did not test their blood sugar daily

Could affect more than **7 MILLION ADULTS**

ESTIMATED IMPACT OF STOPPING DAILY MONITORING

Over five years

10 BILLION
finger sticks avoided

10 BILLION
test strips not used

$1,630
saved per patient in testing supplies

$11.6 BILLION
saved in healthcare costs

REFERENCE

Young LA, Buse JB, Weaver MA, et al. Glucose Self-monitoring in Non–Insulin-Treated Patients With Type 2 Diabetes in Primary Care Settings. *JAMA Intern Med.* 2017;177(7):920.

Analyses carried out by Salutis Consulting, LLC

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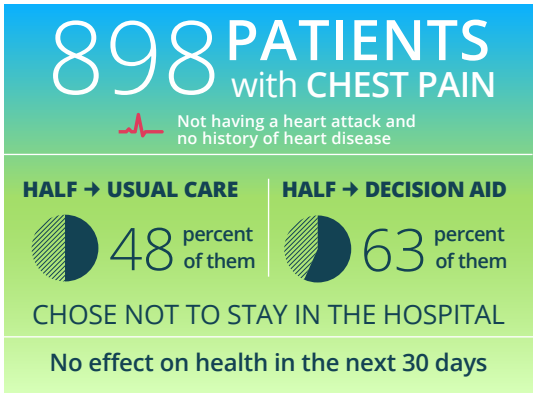
POTENTIAL IMPACT OF PCORI-FUNDED STUDY RESULTS

Using a Decision Aid for Patients with Low-Risk Chest Pain in the Emergency Room

WHAT'S THE ISSUE?

Chest pain is the second-most common reason people visit the emergency department (ED). It accounts for more than 6.5 million visits annually in the United States. Given the potential for missed diagnosis of a serious heart problem, clinicians often recommend admitting patients with chest pain for observation and advanced cardiac testing, even if they are at low risk for having acute coronary syndrome.



WHAT DID THE PCORI-FUNDED STUDY FIND?

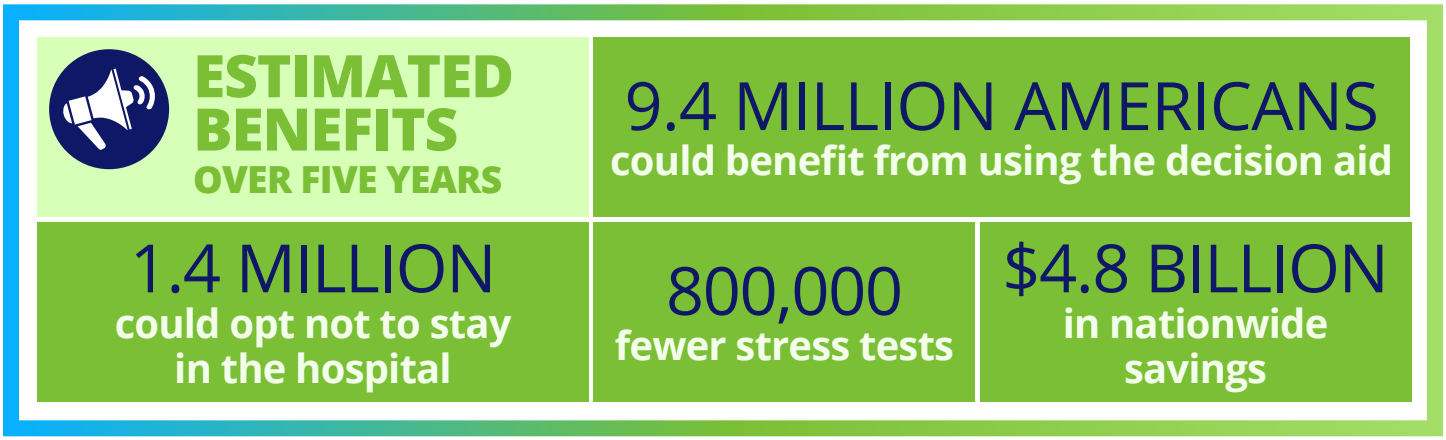
A PCORI-funded study looked at ways to help people who come to the ED with chest pain, but who are at low risk of acute coronary syndrome, make better-informed decisions about follow-up care. The study compared the effectiveness of using a decision aid with usual care in helping patients choose between admission for observation and further cardiac testing or referral for outpatient evaluation. Using the decision aid increased patients' knowledge about their risk, increased patient involvement in decision making, and decreased the rate of admission to an observation unit for cardiac testing. There was no difference in health outcomes within 30 days.

GAUGING THE POTENTIAL IMPACT OF THE RESULTS

Our model of ED visits for low-risk chest pain captured choices made about care, resource use, and costs in the 30 days following the ED visit. We looked at the likelihood of patients undergoing cardiac testing (stress tests and cardiac imaging), coronary artery procedures, and cardiac events.

POTENTIAL CHANGES IN PRACTICE AND COSTS

Using the decision aid with eligible low-risk patients in the ED for chest pain could increase outpatient care while reducing hospital admissions, reducing stress testing, and lowering costs with no change in patients' health in the next 30 days.



REFERENCE

Sources: Hess EP, Hollander JE, Schaffer JT, et al. Shared decision making in patients with low risk chest pain: prospective randomized pragmatic trial. *BMJ.* 2016:i6165.

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POTENTIAL IMPACT OF PCORI-FUNDED STUDY RESULTS

Intravenous versus Oral Antibiotic Therapy for Serious Infections in Children

WHAT'S THE ISSUE?

Clinicians generally treat children with two serious infections—complicated pneumonia and an acute bone infection called osteomyelitis—with intravenous antibiotics when they are in the hospital. When children leave the hospital, however, their care may include antibiotics administered either orally or intravenously via a peripherally inserted central catheter (PICC line). Although long thought to be necessary, PICC lines can be difficult to maintain and can lead to infection and other complications. It has been unclear whether oral antibiotics are as effective as those given through a PICC line.

WHAT DID THE PCORI-FUNDED STUDIES FIND?

PCORI-funded studies showed that, after children left the hospital, there was no difference in effectiveness of oral and IV antibiotics for treating either infection. However, the PICC lines caused complications, such as infection around the IV site, leading many children to need additional hospital care.

GAUGING THE POTENTIAL IMPACT OF THE RESULTS

We modeled the potential impact over five years of reducing the use of PICC lines nationally among children hospitalized with the two infections. These populations include and estimated **20,000 children with acute osteomyelitis and 44,000 children with complicated pneumonia.**

ESTIMATED FIVE-YEAR IMPACT OF CHANGE TO ORAL ANTIBIOTICS

HEALTH

400 Adverse drug reactions avoided

1,800 PICC-related complications avoided

FAMILIES

$165,000 Out-of-pocket costs saved

7,700 Caregiver days* saved

4,600 Additional days children are not in the hospital

UTILIZATION

1,800 Emergency department visits avoided

780 Hospitalizations avoided

EMPLOYERS

23,000 Work hours gained

PUBLIC PAYERS

$6 million Costs saved

PRIVATE PAYERS

$7.6 million Costs saved

$512 Acute osteomyelitis

$74 Complicated pneumonia

Average savings per child

$13.7 million

in potential cost savings

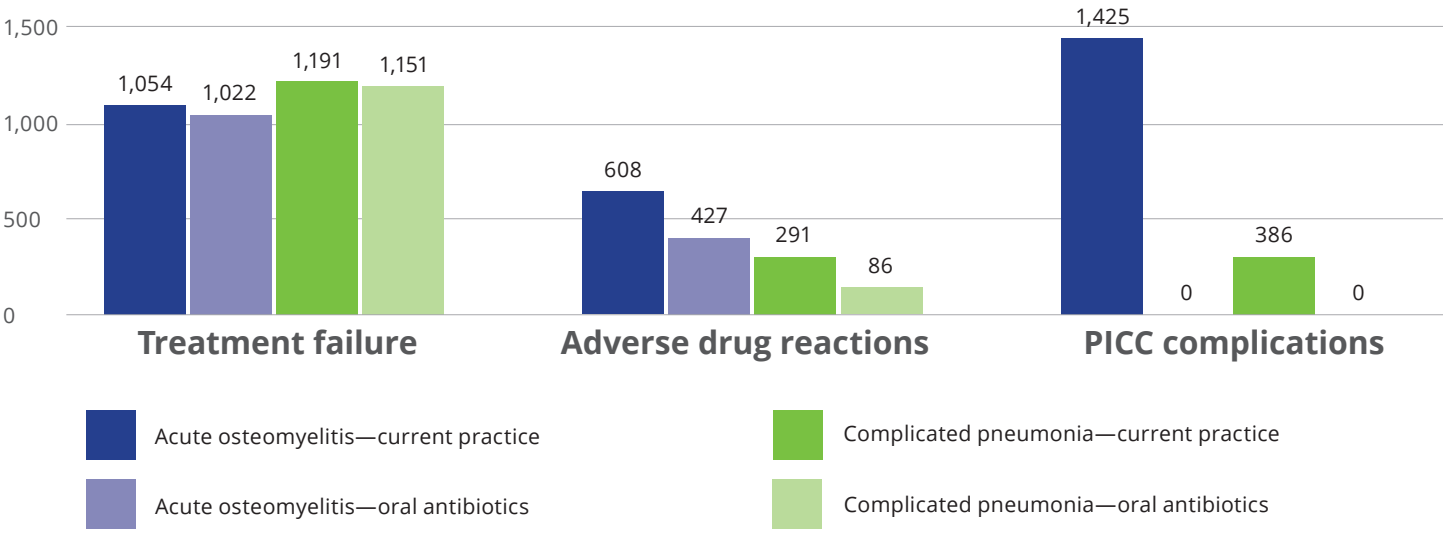
75 percent

reduction in cost of rehospitalization and emergency department visits

** The time caregivers spend with their child in the emergency department or hospital.*

ESTIMATED IMPACT ON CHILDREN'S HEALTH OF CHANGE TO ORAL ANTIBIOTICS

NUMBER OF EMERGENCY DEPARTMENT AND HOSPITAL VISITS AFTER DISCHARGE



ESTIMATED ECONOMIC IMPACT OF CHANGE TO ORAL ANTIBIOTICS *Over five years*

FOLLOWING IMPLEMENTATION OF ORAL ANTIBIOTICS PRACTICE

Healthcare Cost Savings by Payer over Five Years

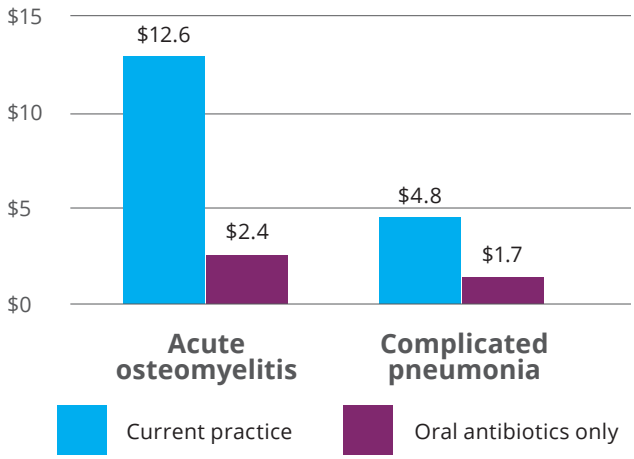
Acute osteomyelitis

- Private payer $5.6 million
- Public payer $4.5 million
- Patient out of pocket $120,000

Complicated pneumonia

- Private payer $1.8 million
- Public payer $1.3 million
- Patient out of pocket $47,000

Total Healthcare Costs over Five Years (in millions)



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1. Keren, R., Shah, S. S., Srivastava, R., et al. (2015). Comparative effectiveness of intravenous vs oral antibiotics for postdischarge treatment of acute osteomyelitis in children. *JAMA Pediatrics,* 169(2), 120–128.
2. Shah SS, Srivastava R, Wu S, et al. Intravenous Versus Oral Antibiotics for Postdischarge Treatment of Complicated Pneumonia. *Pediatrics.* 2016; 138(6):e20161692

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POTENTIAL IMPACT OF PCORI-FUNDED STUDY RESULTS

Comparing Treatments for People with Atrial Fibrillation Who Have Had a Stroke

The study found that people on warfarin had

47.6

more days of home time than did people who were not on warfarin

We estimate

19,600

stroke survivors with AFib would benefit from warfarin treatment

WHAT'S THE ISSUE?

Atrial fibrillation (AFib) affects about 33.5 million people worldwide and causes an estimated 15 percent of all strokes, according to the American Stroke Association. Guidelines recommend most people with AFib take anticoagulants, or blood thinners, to lower their risk of strokes. That risk is four to five times as high among people with AFib who are not treated with anticoagulants as among those who are. But there is limited evidence about using an anticoagulant, such as warfarin, for preventing recurrent strokes among older patients who have already had one. Most but not all people who have had a stroke leave the hospital on warfarin. Because of the well-known benefits of warfarin in preventing an additional stroke, most patients with AFib leave the hospital on warfarin. However, not everyone who might benefit from this now does.

WHAT DID THE PCORI-FUNDED STUDY FIND?

The PCORI-funded study, called Patient-Centered Research into Outcomes Stroke Patients Prefer and Effectiveness Research (PROSPER), compared outcomes among people with AFib who did and did not take warfarin after a stroke. Patients identified the most important outcome to be studied as quality time at home—without recurrent stroke or hospitalization. The study found that people on warfarin had 47.6 more days of time at home than those who weren't on warfarin.

The study included 450 patients. Patients were not included if they:

- Had contraindications for anticoagulation
- Were transferred to other hospitals
- Were receiving comfort measures only
- Were already on regular anticoagulation treatment before their stroke

GAUGING THE POTENTIAL IMPACT OF THE RESULTS

Our simulation model evaluated the potential five-year effect of treating all eligible stroke survivors who have AFib with warfarin after they leave the hospital. Approximately 19,600 US patients would be in this group annually. Applying the study results across all applicable stroke survivors with AFib would increase costs for treatment and monitoring but substantially decrease costs by preventing hospitalizations for recurrent stroke.

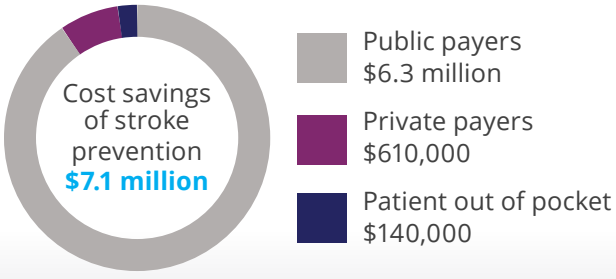
ESTIMATED IMPACT OF FULL ANTICOAGULATION IN TARGET POPULATION

Over five years

470 strokes avoided

4.5 percent reduction in the risk of death from all causes in the 24 months after a stroke

Hospitals would discharge an additional **11,900** patients with AFib on warfarin after a stroke



REFERENCES

1. Xian Y, Wu J, O'Brien EC, et al. Real world effectiveness of warfarin among ischemic stroke patients with atrial fibrillation: observational analysis from Patient-Centered Research into Outcomes Stroke Patients Prefer and Effectiveness Research (PROSPER) study. *BMJ.* 2015;351.
2. Xian Y, O'Brien EC, Liang L, et al. Association of Preceding Antithrombotic Treatment With Acute Ischemic Stroke Severity and In-Hospital Outcomes Among Patients With Atrial Fibrillation. *JAMA.* 2017;317(10):1057.

Analyses carried out by Salutis Consulting, LLC

June 3, 2019

The Honorable Richard Shelby, Chairman
Senate Committee on Appropriations
Room S-128, The Capitol
Washington, D.C. 20510

The Honorable Patrick Leahy, Vice Chairman
Senate Committee on Appropriations
S-146A, The Capitol
Washington, DC 20510

The Honorable Roy Blunt, Chairman
Subcommittee on Labor, Health and Human Services, Education, and Related Agencies
Senate Committee on Appropriations
131 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Patty Murray, Ranking Member
Subcommittee on Labor, Health and Human Services, Education, and Related Agencies
Senate Committee on Appropriations
156 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Shelby, Vice Chairman Leahy, Chairman Blunt and Ranking Member Murray:

On behalf of the undersigned organizations, we wish to urge inclusion of report language that seeks to end patient safety issues related to patient matching in the Senate Fiscal Year 2020 Labor, Health and Human Services, and Education and Related Agencies (Labor-HHS) Appropriations Bills.

For nearly two decades, innovation and industry progress has been stifled due to a narrow interpretation of the language included in Labor-HHS bills since FY1999, prohibiting the U.S. Department of Health and Human Services (HHS) from adopting or implementing a unique patient identifier. More than that, without the ability for clinicians to correctly connect a patient with their medical record, lives have been lost and medical errors have needlessly occurred. These are situations that could have been entirely avoidable had patients been able to have been accurately identified and matched with their records. This problem is so dire that one of the nation's leading patient safety organization, the ECRI Institute, named patient identification among the top ten threats to patient safety.[1]

Importantly, recently proposed rulemakings by both the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) have referenced the existing funding prohibition and have cited the patient matching strategy appropriation report language included in previous Labor-HHS bills to explore new and innovative ways that the Administration can work with industry stakeholders on this critical patient safety and care issue. Moreover, the ability to accurately match patients to their records across the care continuum is an imperative for achieving greater value and better outcomes in our healthcare system and a critical piece of the interoperability puzzle.

The patient matching report language below, which has been included in the House FY20 Labor-HHS bill, clarifies Congress' intent while ensuring that the federal government does not impede private-sector efforts to solve this serious problem. The language enables HHS, acting through ONC and CMS, to provide technical assistance to private-sector led initiatives that support a coordinated national strategy to promote patient safety by accurately identifying patients and matching them to their health

[1] Top 10 Patient Safety Concerns for Healthcare Organizations, Available at: https://www.ecri.org/EmailResources/PSRQ/Top10/2017_PSTop10_ExecutiveBrief.pdf

information. Allowing ONC and CMS to offer this type of technical assistance will help accelerate and scale safe and effective patient matching solutions.

The absence of a consistent approach to accurately identifying patients has resulted in significant costs to hospitals, health systems, physician practices, long-term post-acute care (LTPAC) facilities, and other providers, as well as hindered efforts to facilitate health information exchange. According to a 2016 study of healthcare executives, misidentification costs the average healthcare facility $17.4 million per year in denied claims and potential lost revenue.[2] More importantly, there are patient safety implications when data is matched to the wrong patient and when essential data is lacking from a patient's record due to identity issues. The *2016 National Patient Misidentification Report* cites that 86 percent of respondents said they have witnessed or know of a medical error that was the result of patient misidentification.[3]

Patient identification errors often begin during the registration process and can initiate a cascade of errors, including wrong site surgery, delayed or lost diagnoses, and wrong patient orders, among others. These errors not only impact care in hospitals, medical practices, LTPAC facilities, and other healthcare organizations, but incorrect or ineffective patient matching can have ramifications well beyond a healthcare organization's four walls. As data exchange increases among providers, patient identification and data matching errors will become exponentially more problematic and dangerous. Precision medicine and disease research will continue to be hindered if records are incomplete or duplicative. Further, as our nation combats a growing opioid epidemic, successfully matching patients with their records is critical. Accurately identifying patients and matching them to their data is essential to coordination of care and is a requirement for health system transformation and the continuation of our substantial progress towards nationwide interoperability, a goal of the landmark 21st Century Cures Act.

The ability to identify patients across the care continuum is critical in our efforts to fight the opioid epidemic. Patients being treated for opioid use disorder and patients who have experienced an opioid overdose, for example, may be especially vulnerable and need careful monitoring to help them continue in their recovery and avoid new overdose episodes, both of which hinge in part on the ability to link patients with their complete health data. Appropriately-obtained accurate and complete health data can improve prescribing decisions and help clinicians avoid inadvertently prescribing opioid analgesics to patients with these risk factors. Risk factors could be identified and tracked over time and could enable clinicians to take steps to reduce overdose risks, such as prescribing naloxone, as well as to ensure timely follow-up and save lives.

The quality, safety and cost-effectiveness of healthcare across the nation will improve if a national strategy to accurately identify patients and match those patients to their health information is achieved. Clarifying Congress' commitment to ensuring patients are consistently matched to their healthcare data is a key barrier that needs to be addressed if we are to solve this problem, but not the only one. We the undersigned are committed to working together to identify and address, the various barriers that prevent patient matching today.

We respectfully request that you include the report language below in any FY20 appropriations bill:

---

[2] 2016 National Patient Misidentification Report, Available at: https://pages.imprivata.com/rs/imprivata/images/Ponemon-Report_121416.pdf.
[3] 2016 National Patient Misidentification Report, Available at: https://pages.imprivata.com/rs/imprivata/images/Ponemon-Report_121416.pdf

Clarifying the Unique Patient Identifier Ban to Enable Patient Matching

The Committee is aware that one of the most significant challenges inhibiting the safe and secure electronic exchange of health information is the lack of a consistent patient data matching strategy. With the passage of the HITECH Act, a clear mandate was placed on the Nation's healthcare community to adopt electronic health records and health exchange capability. Although the Committee continues to carry a prohibition against HHS using funds to promulgate or adopt any final standard providing for the assignment of a unique health identifier for an individual until such activity is authorized, the Committee notes that this limitation does not prohibit HHS from examining the issues around patient matching. Accordingly, the Committee encourages the Secretary, acting through the Office of the National Coordinator for Health Information Technology and CMS, to provide technical assistance to private-sector led initiatives in support of a coordinated national strategy for industry and the federal government that promote patient safety by accurately identifying patients to their health information.

We appreciate your consideration and inclusion of this report language and we look forward to working with you to pursue an appropriate solution to enable accurate patient identification and data matching in our nation's healthcare system.

Sincerely,

American Health Information Management Association (AHIMA)
America's Health Insurance Plans (AHIP)
American Medical Association (AMA)
American Medical Informatics Association (AMIA)
Blue Cross Blue Shield Association (BCBSA)
College of Healthcare Information Management Executives (CHIME)
eHealth Initiative (eHI)
EP3 Foundation
Federation of American Hospitals (FAH)
Health Innovation Alliance
Healthcare Information and Management Systems Society (HIMSS)
Healthcare Leadership Council (HLC)
himagine solutions, Inc.
Imprivata
Intermountain Healthcare
Just Associates, Inc.
LTPAC Health IT Collaborative
4medica
Medical Group Management Association (MGMA)
Nemours Children's Health System
NextGate
Patient-Centered Primary Care Collaborative
Premier healthcare alliance
The Sequoia Project
Strategic Health Information Exchange Collaborative (SHIEC)
Trinity Health
Verato
WebShield

June 3, 2019

Submitted via www.regulations.gov

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: CMS–9115–P; Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally Facilitated Exchanges and Health Care Providers

Dear Administrator Verma,

We write to express strong support for CMS' proposal to require hospitals participating in Medicare and Medicaid to send event notifications – also known as admission/discharge/transfer or ADT feeds – to community practitioners. These notifications are critical to improving patient safety through better care transitions and are key to enabling value-based care at scale.

Although our organizations play different roles in the health care system, we are united in a common commitment to realizing the promise of health care data through increased information sharing. We believe that advancing regulations that lead hospitals to share information with community practitioners is a transformative step toward greater data liquidity that will enable better decision-making, reduce waste, and improve outcomes for patients. The benefits of such notifications are evident in states and localities where this information is shared today, and CMS' proposal will ensure that they are experienced by all patients regardless of where they live.

Below we put forth several recommendations designed to further strengthen and refine CMS' approach based on our real-world experience.

1. **Hospitals are able to send ADT notifications today without any new standards or use of certified EHRs to collect data.**

While there are many hospitals that have chosen not to share ADT feed alerts with community providers for competitive or other reasons, states such as Connecticut, Iowa, Wisconsin, Florida, Tennessee, Maryland and New York have already taken steps to encourage hospitals to share ADT feeds with community providers. In other localities, many hospitals are sharing alerts with accountable care organizations (ACOs) and other providers, on their own or through intermediaries.

We stress that hospitals are able to share ADT notifications today using their existing systems, and by working with a health information exchange (HIE) or health information network

(HIN), contracting with a vendor that can send the alerts on their behalf, or building their own interfaces. As evidenced by the widescale adoption of this use case today, new standards efforts are not needed for the successful, immediate implementation of the proposed requirements. In numerous conversations with HIEs, other intermediaries and providers, we were unable to find a single example where a hospital was unable to send an ADT notification today due to lack of standards. For the future, further development of ADT messaging standards could be useful to support inclusion of new data elements and/or types of notifications.

2. **CMS should strike language limiting proposed requirements to hospitals with EHR systems, recognizing that many facilities use other types of systems to send notifications.**

While CMS proposed to limit the new requirements to hospitals that currently possess an EHR system with the capacity to generate the basic information needed for the notification, it is not necessary to use an EHR to gather the required information or send the notification. In fact, many hospitals use administrative IT systems for this purpose. We encourage CMS to strike this language and instead allow hospitals the flexibility to choose how to comply with the new requirement.

3. **Event notifications should be shared for patients who present in the ED regardless of whether they are subsequently admitted as an inpatient, and the minimum information included in the notification should be expanded to include discharge disposition.**

We strongly encourage CMS to expand the patient population to whom this requirement applies to include patients who present in the ED and are subsequently discharged without being admitted, as well as those patients who are admitted in observational status. Planning for a safe care transition begins when a patient presents in the ED regardless of whether they are admitted to the facility. In addition, notifying the community practitioner when a patient visits the ED enables them to intervene immediately which can improve outcomes for the patient and result in better coordination that reduces costs and prevents waste.

We also recommend that CMS expand the minimum information in the notification to include the discharge disposition data field. This information is critical for community providers because it gives insight into the outpatient care recommended to the patient and better enables the provider to follow-up with the patient on their hospital visit and coordinate any additional care.

4. **CMS should consider other policy options for replacing and/or augmenting what constitutes "reasonable certainty" with respect to receipt of notifications.**

We appreciate the need for CMS to establish parameters around a hospital's responsibility for sharing information with community practitioner. While we agree that an exception may be needed when technical issues beyond a hospital's control prevent successful receipt and use of a notification, we are concerned that the "reasonable certainty" standard may not be specific enough to ensure the requirement has the intended effect on information sharing.

Accordingly, we recommend that CMS consider other policy options for replacing and/or augmenting the "reasonable certainty" standard included in the proposed regulation. For example, we encourage CMS to deem a hospital compliant if they send the required information to an intermediary for distribution to their provider networks if the intermediary is covered by the prohibition on information blocking. A hospital would be compliant with the new requirement if they: 1) attest that they are not information blocking through the Promoting Interoperability Program; and 2) generate a notification and share it with the intermediary, but it is not ultimately sent because there is no subscribing provider.

This is an important clarification that ensures hospitals receive credit if they are unable to comply through no fault of their own. It also reinforces that hospitals have discretion in determining the technological mechanism through which they will share notifications; we urge CMS to further clarify this point in the final rule.

5. **CMS should implement a feedback mechanism for community providers to report issues receiving ADT notifications.**

We encourage CMS to consider creating a feedback mechanism for community providers that have the ability to receive notifications yet get incomplete, unreasonably delayed, or no data at all to log or report these issues.

Conclusion

Advancing regulatory levers to promote Medicare and Medicaid-participating hospitals to share ADT feeds has the potential to significantly improve care for patients across the country. CMS' proposed rule is a significant first step on the path to greater information sharing and interoperability. We encourage CMS to implement this new requirement expeditiously (e.g., within months) given that there are no technical barriers to doing so.

Sincerely,

Aledade
American Academy of Home Care Medicine
Audacious Inquiry
Beth Israel Deaconess Care Organization
Biden Cancer Initiative
Blue Shield of California
Caregiver Action Network
Community Care Collaborative of Pennsylvania and New Jersey
Elation Health
Florida Association of ACOs
Greater Houston Healthconnect
Healthix
Iora Health
Keystone ACO
Lahey Clinical Performance ACO

Lahey Clinical Performance Network
MaineHealth Accountable Care Organization
Manifest Medex
Mental Health America
Missouri Health Connection
National Association of Accountable Care Organizations
National Council for Behavioral Health
National Partnership for Women & Families
NEQCA Accountable Care, Inc.
Network ACO
OneHealth Nebraska
Partnership to Empower Physician-Led Care
Patient-Centered Primary Care Collaborative
PatientPing
Rhode Island Quality Institute
RGV ACO Health Providers, LLC
Saint Francis Healthcare Partners
The Health Collaborative

June 3, 2019

Donald Rucker, MD
National Coordinator
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Mary E. Switzer Building
330 C Street SW
Washington, DC 20201

RE: RIN 0955-AA01: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

Dear National Coordinator Rucker:

Our organizations—which represent physicians, nurses, hospitals, public health professionals, and other stakeholders—encourage the Office of the National Coordinator for Health Information Technology (ONC) to prioritize patient safety as part of its efforts to implement new criteria for electronic health records (EHRs) used in the care of children.

Given that the care of children can differ significantly from that of adults, the technology used by clinicians should account for that variation. For example, children often receive medication doses based on their weight. Similarly, chronological or gestational age may be used for medication dosing in highly vulnerable premature infants. The EHRs used to prescribe those drugs should account for these critical dosing differences, which—coupled with the use of technology that is not geared towards these unique variations—can contribute to medical errors in pediatric care.

Safety problems associated with the use of EHRs in pediatrics often stem from system usability, which refers to how the technology can be effectively and efficiently used by clinicians. System layout, customizations, facility workflows, and many other factors can affect EHR usability for pediatric providers.

Poor usability can have significant negative consequences. It can contribute to clinician burden when using systems, which can harm the efficiency and quality of care. Poor usability can also contribute to medical errors. Research published in the November 2018 edition of *Health Affairs* showed that EHR usability contributed to medication errors in 3,243 of 9,000 safety events examined across just three health care organizations that care for children.[1] Additionally, recent examples of EHR usability-related medical errors showcased pediatric-specific challenges, such as with newborn care and weight-based dosing.[2]

Recognizing this challenge, Congress—via the 21st Century Cures Act (Cures) passed in 2016—required ONC to establish voluntary certification criteria for EHRs used in pediatric settings. To implement this provision, the ONC proposed rule identifies 10 clinical priorities for pediatric care. ONC also included worksheets to map each of these clinical priorities to existing and proposed requirements for EHRs. For example, ONC proposes that EHRs used in pediatric care should have the ability to compute the weight-based dosage of a medication and could use EHR functions for electronic drug prescribing with pediatric vital signs to meet this clinical priority.

While we generally support the 10 clinical priorities identified by ONC for pediatric care, including weight-based drug dosing, tools to support growth charts for children, and age-based dose checking, we

assert the agency can take additional steps to improve patient safety and system usability for EHRs used in the care of children. These include:

- **Mapping additional existing EHR certification requirements to pediatrics**
  ONC should further extend the approach taken in the proposed rule to map the agency's existing EHR certification requirements to pediatric care. For example, ONC currently requires that all EHR developers test their system using predefined scenarios that mimic real-world situations. ONC should clarify that demonstrating adherence to the 10 clinical priorities must involve pediatric-focused scenarios. Similarly, ONC currently requires that EHR developers test their system with end-users, such as physicians and nurses. ONC should clarify that EHR developers must involve end-users that care for children—such as pediatricians and pediatric nurses—in the testing of the identified clinical priorities in pediatric care.

- **Providing additional pediatric-focused resources**
  ONC should ensure that the appropriate resources are available to support meeting pediatric-focused criteria. For example, ONC should develop specific and detailed guidance for each proposed pediatric clinical priority. In addition, ONC should involve pediatric usability experts in the development of implementation guides and test procedures for the pediatric clinical priorities.

Conclusion
Cures directed ONC to address deficiencies in the use of technology in pediatric settings. By incorporating these additional recommendations into its development of a pediatric EHR certification program, ONC can take concrete steps to improve the usability of EHRs used in pediatric care to both reduce clinician burden and prevent medical errors.

Thank you for the opportunity to comment on the proposed rule to implement new criteria for EHRs used in the care of children. Should you have any questions or if we can be of further assistance, please contact Ben Moscovitch, director, health information technology, The Pew Charitable Trusts at bmoscovitch@pewtrusts.org or 202.540.6333.

Sincerely,

American Academy of Pediatrics
American Nurses Association
Arkansas Children's Hospital
Children's Hospital Association
Drummond Group
Medical Group Management Association
MedStar Health
Patient-Centered Primary Care Collaborative
The Pew Charitable Trusts
The University of Texas, UT Health Austin

[1] Raj M. Ratwani et al., "Identifying Electronic Health Record Usability and Safety Challenges in Pediatric Settings," *Health Affairs* 37, no. 11 (2018: 1752-1759, https://doi.org/10.1377/hlthaff.2018.0699.
[2] The Pew Charitable Trusts, "Poor Usability of Electronic Health Records Can Lead to Drug Errors, Jeopardizing Pediatric Patients," (April 2019), https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2019/04/poor-usability-of-electronic-health-records-can-lead-to-drug-errors-jeopardizing-pediatric-patients.

May 30, 2019

Submitted via DPC@cms.hhs.gov

Mr. Adam Boehler
Deputy Administrator for Innovation & Quality
Director, Center for Medicare and Medicaid Innovation
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Geographic Population-Based Payment (PBP) Model Option Request for Information (RFI)

Dear Deputy Administrator Boehler:

Thank you for the opportunity to respond to the RFI on Direct Contracting – Geographic PBP Model Option. We applaud your commitment to pursuing payment and delivery system reform through innovative demonstration programs.

Our organizations are deeply committed to value-based care. We believe that effective, efficient primary care is key to improving outcomes and reducing costs, and we were pleased to see the Center for Medicare and Medicaid Services (CMS) focus on these critical health care services in its new models.

As you move forward in implementing this model, we strongly urge you to consider the impact on provider competition. As required by the Executive Order on Healthcare Choice and Competition, the Administration released a report in November 2018 outlining key recommendations for strengthening our health care system through increased competition.[1] The report recommended that the Administration ensure that delivery system reform models "foster collaboration across systems within a geographic area and do not produce harmful consolidation…, " and that the Administration ensure that smaller physician and provider practices are not "unduly harmed" by delivery system reform requirements.

We are pleased that you intend to give preference to direct contracting entities (DCEs) in target regions with more than one DCE, but believe that additional guardrails may be necessary to preserve choice and competition for traditional Medicare beneficiaries. For example, geographic DCEs should not be allowed to use their market power to mandate or require providers in a specific area to contract with them, or to require patients to see providers with whom they have a negotiated relationship. Any geographic demonstration should be closely monitored for unintended consequences and shifting competitive dynamics to ensure that it does not fuel provider consolidation trends already contributing to high costs in the commercial market.

We also strongly urge you to consider the implications of model overlap in a particular region. Geographic DCEs should not displace or take precedence over existing risk-taking entities working to achieve value-based care such as accountable care organizations (ACOs) and professional or global DCEs. Participants in existing models, including many physician-led groups, have made significant investments to shift to value-based care. These investments should be recognized by new models and model participants coming into a target region. We encourage CMS to continue to directly contract with ACOs in the Medicare Shared

[1] U.S. Departments of Health and Human Services, Labor and Treasury, "Reforming America's Healthcare System Through Choice and Competition." Available here: https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf

Savings Program, the Next Generation ACO Program and other CMMI models. Any disruption in an existing model inevitably distracts from the important work of creating more value for Medicare beneficiaries.

Thank you again for the opportunity to provide input. We look forward to work with CMS as you further develop this model.

Sincerely,

Alliance for Innovative Primary Care
American Academy of Family Physicians
Medical Group Management Association
National Association of Accountable Care Organizations
Next Generation ACO Coalition
National Coalition on Health Care
Partnership to Empower Physician-Led Care
Patient-Centered Primary Care Collaborative

CENTER FOR HEALTHCARE QUALITY & PAYMENT REFORM

The Problems with "Primary Care First" and How to Fix Them

May 2019

Harold D. Miller

The Need to Improve Payment for Primary Care Services

The most important element of a truly "value-based" healthcare system is strong primary care. The reason is simple – the lowest spending and the best outcomes occur when patients stay healthy, and primary care is the only component of the healthcare system that is specifically designed to help patients prevent health problems from occurring and to identify and treat new problems as early as possible.

Unfortunately, the nation's primary care system is at risk of collapse. There is a large and growing shortage of primary care physicians in the country[1]; many primary care physicians are burning out[2], and most medical students don't want to go into primary care[3]. Although there are multiple causes for this, a major reason is the failure of the current payment system to provide adequate resources to support high-quality primary care services.[4] The problems are particularly severe for small primary care practices, which deliver most of the care in rural areas of the country.

The CMS "Primary Cares Initiative" and "Primary Care First"

On April 22, 2019, Secretary of Health & Human Services Alex Azar announced the "CMS Primary Cares Initiative," consisting of five new payment model options intended to "transform primary care to deliver better value for patients throughout the healthcare system."[5] Two of the payment model options are titled "Primary Care First," and the others are called "Direct Contracting." Following the announcement, many stakeholder groups praised HHS and CMS for creating multiple new primary care payment options, since the only current CMS alternative payment model for primary care is the Comprehensive Primary Care Plus (CPC+) initiative, and it is only available to primary care practices in a small portion of the country.[6]

The full specifications of the new Primary Cares Initiative options have not yet been released, but based on the details CMS has revealed so far,[7] it appears they may fall far short of what is needed to fully address the problems facing primary care and to successfully sustain a high-value primary care system.

Essential Elements of a Good Primary Care Payment System

What should the payment system for primary care look like? Both the American Academy of Family Physicians (AAFP)[8] and Jean Antonucci, MD[9] (a solo primary care physician practicing in rural Maine) have developed proposals for new primary care payment models that the Physician-Focused Payment Model Technical Advisory Committee (PTAC)[10] recommended be implemented by HHS.[11] These proposals, as well as proposals developed previously by other primary care physicians and experts on primary care payment,[12] have five key elements in common:

1. **Flexibility to Deliver Services to Patients Other Than Traditional Face-to-Face Office Visits.** Instead of being paid only for face-to-face office visits with physicians, primary care practices should receive a monthly payment for each patient that provides flexibility for the primary care provider (PCP), a nurse, or other staff to help the patient in person, by phone, or by email. The practice should receive this payment for every patient who agrees to receive primary care from the practice.
2. **Adequate Resources to Support Essential Services.** In order for primary care practices to have adequate staff and sufficient time to provide high-quality care for patients, the monthly payments need to provide two to three times as much revenue as the practices currently receive from office visit fees. In addition, since patients with more health conditions and other challenges will require more time and services from their primary care practice, a primary care practice will need to receive a higher payment for each higher-need patient.
3. **Accountability Focused on Patient-Centered Outcomes the Practice Can Control.** A primary care practice that receives adequate, flexible payments can and should be accountable for delivering high-quality care, helping its patients achieve good outcomes, and for reducing avoidable spending. However, primary care practices should not be placed at financial risk for aspects of spending they cannot control or influence.
4. **Reasonable Administrative Burden.** Primary care practices should be able to spend as much of their time as possible on activities that will improve patient care rather than on burdensome administrative tasks.
5. **Consistent, Predictable Payments.** Primary care practices should know in advance how much they will be paid if they deliver high-quality care so they will know how much they can afford to spend on staff, equipment, and other costs.

SUMMARY OF PROBLEMS WITH PRIMARY CARE FIRST AND HOW TO FIX THEM

Essential Elements of a Good Primary Care Payment System	Problems with Primary Care First	Changes to Improve Primary Care First
1. Flexibility to deliver services to patients other than traditional face-to-face office visits	• Practices would still receive more than one-third of their revenues based on the number of face-to-face office visits • For many patients, payments would still be primarily based on face-to-face office visits • Most primary care practices in the country would not be able to participate	• Pay practices with a monthly per-patient payment in place of all fees for office visits • Begin paying monthly payments immediately for each patient who enrolls for care from the practice • Allow primary care practices in all parts of the country to participate
2. Adequate resources to support essential services for patients (significantly higher than provided by current payments)	• Most practices would receive no more revenue than they do today • Practices would no longer receive a higher payment for a patient who has greater needs	• Set monthly payment amounts at levels adequate to support high-quality primary care • Pay a higher monthly amount for a patient who has greater needs • Create a complementary payment model with adequate payments to support home-based palliative care for seriously ill patients
3. Accountability focused on patient-centered outcomes that a primary care practice can control	• Most practices would not receive higher payments based on performance • Performance measures used for accountability are not patient-centered and cannot be fully controlled by primary care practices	• Use measures of patient-centered outcomes that can be controlled by the practice in order to evaluate its performance • Set achievable performance targets, adjusting appropriately for the number and characteristics of the patients in the practice
4. A reasonable administrative burden for the primary care practice	• Payment complexity would increase and administrative burdens would remain high	• Create new billing codes so that practices can use existing billing systems for both monthly payments and the fees they will continue to receive
5. Consistent, predictable payments	• Practice revenues could vary significantly from quarter to quarter based on random variation in hospitalization rates, factors outside the practice's control, and the performance of other practices	• Increase payments annually based on inflation • Allow practices to determine which patients have higher needs that require higher payments • Set performance targets in advance • Prevent practices from being penalized or rewarded for random variation in outcomes • Limit performance-based payment adjustments to 15% of base payments

The Problems with Primary Care First

Although there are five different payment model options in the Primary Cares Initiative, the two "Primary Care First" options are the only ones that a small primary care practice will be able to participate in. The "Direct Contracting" options are only available to practices that have at least 5,000 Medicare patients, which is far more patients than solo and small primary care practices will have and more than many practices in rural communities will have. In fact, most of the counties in the United States don't even have 5,000 Medicare beneficiaries living in them.[13]

Unfortunately, based on the information released so far, Primary Care First doesn't have the characteristics of a good primary care payment model described above. There are nine important gaps in the current design:

1. Practices Would Still Receive a Significant Portion of Revenues Based on the Number of Face-to-Face Office Visits

As Primary Care First is currently defined, a participating primary care practice will receive a $24 "Professional Population-Based Payment" (PBPM payment) each month for each attributed patient instead of being paid current Medicare fees for Evaluation & Management (E/M) services and office visits. The monthly payment would give the practice flexibility to deliver services that are not eligible for Medicare payment today, such as phone calls, emails, care management, etc.

However, at the same time that Primary Care First eliminates the current E/M payments for face-to-face office visits for attributed patients, it creates a brand-new $50 fee for each face-to-face office visit, which is about half as much as the average amount primary care physicians currently receive from Medicare for office visits.[14] Based on the current average frequency with which Medicare beneficiaries make primary care office visits, this means that more than 40% of a typical practice's payments would still be tied to face-to-face visits.[15] As a result, if the practice is able to care for patients effectively with fewer office visits, it will lose revenue and it could be unable to cover its operating costs.

This hybrid payment model is not what primary care practices have called for, because it does not provide the kind of flexibility that they need to truly redesign care delivery. Under the current design of Primary Care First, a practice that successfully keeps its patients healthy and enables chronic care patients to receive services at home rather than in a hospital or the physician's office could be financially penalized compared to practices that continue to rely heavily on traditional office visits to deliver services. Moreover, this hybrid payment approach is already being tested in CPC+ Track 2, where the practice receives a quarterly per-patient Comprehensive Primary Care Services Payment in addition to lower E/M payment amounts.

2. Payments for Many Patients Would Not Be More Flexible at All

Although the PBPM payments would provide a practice with some greater flexibility to deliver different services than would be possible with E/M payments alone, the practice would only receive the flexible PBPM payments for patients who are "attributed" to the practice or who "voluntarily align" with the practice. Patients are only attributed to the practice if most of their primary care visits during the previous two years were made to that same practice. For example, a patient will only be attributed to a practice in the first quarter of 2020 if the patient received more primary care visits from that practice than any other practice during the 24-month period between October 2017 and September 2019 or if the patient received their most recent Annual Wellness Visit during that time period from the Primary Care First practice. This means that a patient who switched their care to the Primary Care First practice in 2019 may not be attributed to that practice until 2021, and there would be no change in the payment to the practice for that patient until then.

A patient can also "voluntarily align" with the practice, which would override the attribution process. However, the patient cannot simply sign a form designating the practice as their primary care provider. The patient has to create an account on the CMS website and go through a multi-step process to designate the PCP as their primary clinician. Even if the patient successfully completes this process, the patient will not be included on the practice's attribution/alignment list for up to six months after the patient makes the designation.[16]

As a result of these complex rules, a significant subset of a primary care practice's patients may not be formally attributed/assigned to it, and it will not receive the monthly PBPM payments for those patients. Instead, it will only be able to receive traditional E/M fees for these patients, with no flexibility to deliver care differently. This, combined with the office visit fee for the attributed/aligned patients, means that the majority of the practice's revenues for Medicare beneficiaries will likely still be based on how many face-to-face office visits patients make. Moreover, unless all of the practice's other payers make changes similar to Primary Care First, the vast majority of the practice's revenues will still be based on traditional, narrowly-defined fee-for-service payments.[17]

3. Practices Would No Longer Receive a Higher Payment for a Patient Who Has Greater Needs

In the current fee-for-service payment system, in the CPC+ demonstration, and in both of the primary care payment models developed by the AAFP and Dr. Antonucci, a primary care practice would receive a higher payment when it provides care to a patient with greater needs:

- Under the current fee for service system, a primary care practice is paid more for a patient with higher needs because (a) the patient will likely need to make more visits to the practice, (b) the visits will likely be

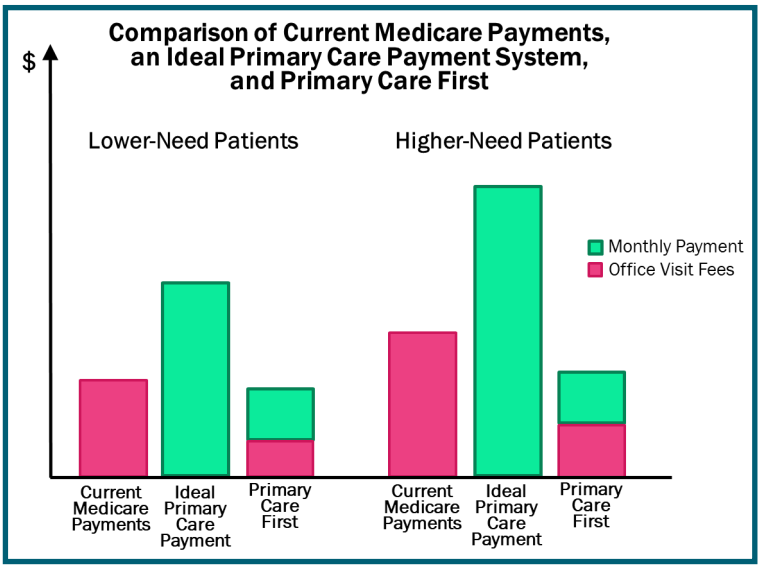
longer and more complex, and thereby eligible for higher Medicare payments, and (c) the practice will also be able to bill for additional Chronic Care Management payments for many of those patients.

- In the current CMS Comprehensive Primary Care Plus (CPC+) initiative, primary care practices receive a Care Management Fee (CMF) for each patient in addition to fee-for-service office visit payments, and the CMF is up to 5-10 times higher for a patient who has multiple health problems than for a patient who is relatively healthy.
- In the primary care payment models developed by both the AAFP and Dr. Antonucci, a practice would receive a higher monthly payment for each patient who has greater needs for care.

Yet under Primary Care First, a primary care practice would receive the exact same monthly payment for a patient regardless of how sick or healthy they are. A practice could receive a higher monthly payment for *all* of its patients if a sufficiently large fraction of its patients are sufficiently sicker than average to bump the practice into a higher payment tier, but it would not receive a higher payment for an *individual* patient who was much sicker than average. Since an individual patient who has higher needs will require more time and resources from the practice than other patients, a practice that is caring for that patient will have to reduce the time and resources it devotes to other patients if the payment is the same.

CMS has not yet defined what average risk score among the patients would trigger a higher monthly payment to the practice in Primary Care First. Even if the average risk score for the practice's patients was high enough to qualify for the next higher level of payment, that would only be $28 per patient per month instead of $24. If the average risk score for *all* patients is high enough, the practice could receive payments of $45 per month, $100 per month, or even $175 per month for every patient. However, it seems unlikely that many practices, particularly small practices, would have so many very ill Medicare patients that they could qualify for the payments at these levels. If payment levels of $45 per month, $100 per month, or $175 per month are appropriate when all of the patients in the practice have an average risk score of a certain level, then it would be inappropriate to only pay $24 or $28 per month for an individual patient who has high needs simply because the other patients in the practice don't have similar needs.

Moreover, Primary Care First will use the CMS Hierarchical Condition Category (HCC) system to determine a patient's risk score, and HCCs are based only on the number of chronic conditions that a patient had in previous years, not their current chronic conditions, the severity of those conditions, the acute conditions they are currently experiencing, their functional status, or other barriers they face in obtaining care.[18] As a result, a practice could have a very high need group of patients, but still receive no higher payment under Primary Care First because the higher needs of the patients would not be reflected in their HCC scores.



In addition, under Primary Care First, the practice would receive the exact same $50 office visit fee regardless of how much time is required to address the patient's needs. In contrast, under the current Medicare Physician Fee Schedule, a practice can receive as much as $148 for a Level 5 visit with an established patient and $210 for a Level 5 visit with a new patient. In 2018, CMS proposed replacing E/M office visit fees for all physicians with a single flat fee, but it withdrew this change following widespread criticism that this would financially penalize physician practices that have higher-need patients and make it more difficult for such patients to obtain primary care services. These problems would presumably be even greater under Primary Care First, since the practice would receive an even lower amount per visit and the same $24 per month payment regardless of a patient's needs.

CMS has also created a second option under Primary Care First for "Seriously Ill Patients." In this option, practices would receive $275 per patient per month in addition to the $50 visit fees, but this would only apply to seriously ill patients who do not already have a primary care provider. Although this payment amount would be much higher than the default payment of $24 per patient per month, it is actually far below the amount needed to support the kind of home-based palliative care services these patients need, much less all of their primary care needs, too. Payment models for home-based palliative care developed by both the American Academy of Hospice and Palliative Medicine (AAHPM)[19] and the Coalition to Transform Advanced Care (CTAC)[20] included payments of at least $400 per month to support palliative care services to a patient with advanced illness.

4. Most Practices Would Receive No More Revenue Than They Do Today, and Less Revenue Than Under Other CMS Primary Care Models

While opinions differ about the best methodology for paying for primary care, there is widespread agreement that primary care practices need to be paid more than

they are paid today. Under the CMS Comprehensive Primary Care Plus initiative, primary care practices are paid 30% - 60% more for attributed/aligned patients than they would typically receive under the current fee-for-service system. Both the AAFP and Antonucci primary care proposals call for even higher payment amounts than this.

However, it appears that under Primary Care First, a primary care practice would receive no increase in revenue. Under Primary Care First, a primary care practice would receive less than $43 per patient per month for each attributed patient, compared to average revenues of $35 - $46 per patient per month under the current Medicare Physician Fee Schedule.[21] In fact, CMS has indicated that the combination of the PBPM payments and office visit fees in Primary Care First is intentionally designed to be equivalent to the current fee-for-service payments that practices receive. Moreover, because the PBPM payment would be the same for all patients, practices whose patients have required more and/or longer visits than average would likely receive less revenue under Primary Care First than they do today.

This also means that primary care practices would receive lower payments under Primary Care First than they do under CMS's existing Comprehensive Primary Care Plus (CPC+) initiative:

- In Track 1 of CPC+, a practice would receive Care Management Fees averaging $15 per beneficiary per month on top of E/M visit-based payments (which would typically average about $35 PBPM), for average total payments of about $50 per patient per month.
- In Track 2 of CPC+, a practice would receive a combination of E/M visit-based payments at a reduced rate and a quarterly Comprehensive Primary Care Payment, plus Care Management Fees averaging $28 per beneficiary per month, resulting in average total payments of about $62 per patient per month.
- In contrast, in Primary Care First, the $24 monthly payment per patient and the $50 per visit fees would generate average total payments of only about $43 per patient per month, which would be 14% - 31% less than practices participating in CPC+.

Despite receiving no additional revenue, a Primary Care First practice would be expected to deliver the same kinds of expanded services required under CPC+, including 24/7 access to a care team member, care management services, and integrated behavioral healthcare services.

5. Most Practices Would Receive Little or No Reward Based on Their Performance

Primary Care First also includes a "Performance-Based Adjustment" which could increase the amount the practice is paid by as much as 50%. However, it appears that at most a small fraction of practices would receive an increase that large because of the way the criteria are being defined:

- Two-thirds of the Performance-Based Adjustment would be based on how often a practice's patients are hospitalized relative to other practices participating in the program. Only half of participating practic-

PERFORMANCE-BASED ADJUSTMENTS TO PAYMENTS IN PRIMARY CARE FIRST

		Quality & Cohort Adjustments	Improvement Adjustment	Total Performance-Based Adjustment
Quality Measures	Worse than minimum standard	-10%	0%	-10%
Hospitalization Rate Compared to Primary Care First (PCF) Practices	Worst 25% of practices nationally	-10%		
	Worse than 50% of PCF Practices	**0%**		
	Better than 50% of PCF Practices	+ 6.5%		
	Better than 60% of PCF Practices	+13%		
	Better than 70% of PCF Practices	+20%		
	Better than 80% of PCF Practices	+27%		
	Better than 90% of PCF Practices	+34%		
Achievement of Hospitalization Rate Improvement Goals Compared to Other Primary Care First Practices	**Bottom 60% of PCF Practices**		**+ 3.5%**	
	Better than 60% of PCF Practices		+ 7%	
	Better than 70% of PCF Practices		+10%	
	Better than 80% of PCF Practices		+13%	
	Better than 90% of PCF Practices		+16%	
			MAXIMUM REDUCTION	-10%
			MAXIMUM INCREASE	+50%
			CHANGE FOR MAJORITY OF PRACTICES	+3.5%

es would even be eligible for this "Cohort Adjustment," and at most 10% of practices would be able to receive the maximum payment increase of 34%.[22] No matter how much the practice reduced the hospitalization rate for its patients, it would only receive an increased payment under the Cohort Adjustment if the hospital admission rate for its patients was lower than the hospitalization rate at other practices. The majority of practices would receive an increase of either 0% or 6.5% for this component.

- The remaining one-third of the Performance-Based Adjustment would be based on whether the practice achieved an "improvement target." CMS has not yet defined how this improvement target would be set, but regardless of the details, CMS has said that at most 10% of practices would be eligible for the maximum payment increase of 16% (and these would not necessarily be the same practices that had qualified for the maximum Cohort Adjustment). By definition, the majority of practices would be eligible for only a 3.5% payment increase on this component.[23]

As a result, it appears that the majority of practices would only be able to receive a 3.5% increase in their total payments through the Performance Based Adjustment component of Primary Care First, not a 50% increase. This is less than the Performance Based Payments practices can receive under the Comprehensive Primary Care Plus Initiative, which are equivalent to about 5-7% of the revenue a CPC+ practice would receive from visit-based payments and care management fees. In the first year of the CPC+ program, most practices were not able to achieve the rates of ED visits and hospitalizations necessary to retain the portion of the performance-based payment that is based on utilization.[24]

Across all practices, it appears the average Performance-Based Adjustment in Primary Care First would be about 17%. This is a bigger percentage increase than the maximum Performance-Based Payment under CPC+; however, because the base payments in Primary Care First would be 14%-31% lower than in CPC+, practices in Primary Care First would still be receiving less revenue in total than practices participating in CPC+. The small percentage of practices that receive the maximum 50% Performance Based Adjustment in Primary Care First would be receiving about the same amount in total payments as a high-performing practice that participates in CPC+ Track 2.

6. Accountability Measures Are Not Patient-Centered

Under Primary Care First, a practice that performs well on quality measures would not automatically receive a higher payment because of that. Delivering high-quality care would merely enable the practice to *avoid a reduction in payment*; the practice would only qualify for an *increase in payment* if its patients were also hospitalized less frequently than the patients in other practices. As noted earlier, the majority of practices would only be eligible for a small increment in payment based on hospitalization rates, so for most practices, delivering care that is better than minimum quality standards would not result in a significant difference in payment. (In the first year of the Primary Care First program, a practice with a low rate of hospital admissions can qualify for a large increase in payment even if the overall quality of care it delivered was poor.)

Moreover, "quality" would be determined using at most five quality measures (control of hemoglobin A1c for diabetic patients, control of blood pressure, colon cancer screening, existence of an advanced care plan, and patient ratings of their care experience; the diabetes and colon cancer screening measures would be dropped for practices whose patients have high average risk levels, leaving only three quality measures for the highest-risk patients). While this short list would limit the administrative burden of quality measurement, it would also give primary care practices an undesirable incentive to focus more attention on diabetic and hypertensive patients than on patients who have other kinds of health problems or who are at risk of developing problems.

Although Primary Care First has been described as "outcome-based payment," the Performance-Based Adjustment would be determined based on only one narrowly-defined outcome -- whether a patient is hospitalized or not. The hospitalization rate used in determining the amount of the adjustment is a very crude measure that does not distinguish whether a hospitalization could have been avoided by the primary care practice. A hospital admission for injuries in a traffic accident, for planned surgery to treat cancer, or for complications of chemotherapy administered by an oncologist are treated the same as an admission for an exacerbation of a chronic disease due to the PCP's failure to prescribe appropriate medications. Analyses have shown that the majority of hospital admissions for Medicare beneficiaries are not in the categories considered to be potentially avoidable.[25]

The heavy weight placed on this one measure appears to be intentionally designed to give primary care practices a large financial incentive to focus their attention on those patients who have a high risk of hospitalization for avoidable reasons. However, since a primary care practice in Primary Care First would not receive higher payments than it does today, this could force the practice to reduce services to other patients in order to fund care management services focused on the high-risk patients.

Moreover, although all patients would like to avoid *unnecessary* hospital admissions, hospital admissions are necessary in many cases to safely treat serious problems, and delaying or discouraging these admissions would negatively affect patients. Recent studies have suggested that financial incentives to reduce hospital readmissions for patients with chronic conditions may have increased the mortality rate for those patients.[26]

7. Practice Revenues Would Be Unpredictable and Uncontrollable

Most of the costs in a primary care practice are fixed. Personnel, rent, and equipment leases all need to be paid every month, and these costs don't vary depending on the number of office visits patients make or the number of other services they receive. One of the important benefits of paying a practice using monthly payments per patient, rather than traditional fees for individual services, is that monthly payments are better aligned with the way the practice incurs costs.

However, a primary care practice needs to be able to predict how much it will receive each month in order to be sure it will have enough revenues to cover the costs of hiring additional personnel to deliver expanded services to its patients. Several aspects of the current design for Primary Care First will make it impossible for primary care practices to predict or control how much they will be paid from month to month:

- The practice will only receive the monthly Professional Population-Based Payment for patients who are attributed to the practice or who complete the voluntary alignment process. Based on the experience of other programs that use similar attribution methods, including CMS primary care models, a significant proportion of the patients a practice sees will not be attributed to it.[27]
- Even if a patient is attributed/aligned with the practice, CMS will reduce the practice's monthly payment if the patient receives services from other physician practices, and the practice may not be aware of this until after it occurs.[28] A recent study found that adjustments in payments to primary care practices based on whether patients made visits to other practices or an Emergency Department simply penalized those primary care practices that had more high-need patients.[29]
- A practice could receive a 10% reduction in payments if its performance fell below minimum levels on quality measures that depend on the ability of its patients to afford medications, obtain cancer screening, and adhere to care plans. In the first year of the CPC+ program, 14% of practices did not have quality performance levels sufficient to retain any of the Quality Component of their Performance-Based Payment.
- Any increase in payment would depend not on whether the hospitalization rate for the practice's patients was high or low, but whether it was higher or lower than the hospitalization rates for other participating practices, so even if a practice reduced the rate of hospitalization for its patients, it wouldn't know how much of a payment adjustment it would receive until after the rates were determined for all Primary Care First practices. Moreover, this "tournament" approach to performance-based payment can also discourage collaborative efforts to improve primary care, since practices will only receive bonuses if other practices have poorer performance.
- The hospital admission measure is "risk adjusted" using a variation of the CMS Hierarchical Condition Category (HCC) risk adjustment system. Multiple studies have shown this type of claims-based risk adjustment methodology inappropriately penalizes providers who serve patients who have low functional status, limited access to community services, and other types of disadvantages.[30] As a result, a primary care practice may have a high or low admission rate and experience increases or decreases in the admission rate for reasons that are beyond the control of the practice.
- The practice's payments would increase or decrease by 7% depending on whether the hospitalization rate for the practice's patients fell into a higher or lower performance decile.[31] Most of the performance deciles would only differ by small amounts. Since the hospital admission rate for the same group of patients can vary significantly from year to year due purely to random factors beyond the control of a practice, a practice's revenues could increase or decrease frequently and unpredictably. In a small practice, unexpected hospitalizations for one or two patients could result in a 7% cut in the practice's revenues.[32]
- The Performance-Based Adjustment would be based on patients who are attributed to the practice, and some patients who are no longer receiving services from the practice could still be attributed to the practice for up to two years. The practice would be penalized if these patients are hospitalized even though they are no longer under the care of the practice.

8. Payment Complexity Would Increase and Administrative Burdens Would Remain High

CMS says that Primary Care First will "allow clinicians to focus on caring for patients rather than their revenue cycle." However, the practice's "revenue cycle" will actually become more complex than it is today:

- Participating practices would still need to bill for all current E/M visit codes for the patients they see who are not attributed/aligned with the practice.
- Practices would presumably need to use a new billing code for office visits with attributed/aligned patients in order to receive the $50 per visit fee. This would require the practice to determine which patients qualify for which codes.
- Practices would have to regularly review attribution/alignment lists in order to determine if they have received the correct number of monthly payments for their patients, and request corrections from CMS if there are errors in the list.
- Practices would still need to bill for all tests and procedures they perform, since the monthly payments and office visit fees are only intended to replace payments for evaluation & management services, not all of the services a practice delivers.
- Practices would still need to submit standard bills for all visits, tests, and procedures they deliver to patients who are insured by health plans that do not participate in Primary Care First or use the same payment methodology as CMS.

As a result, it is unlikely that primary care practices in Primary Care First would experience any reduction in

costs related to billing for services.

9. Most Primary Care Practices in the Country Will Be Unable to Participate

Even if a primary care practice wants to participate in Primary Care First, it will not be able to do so if it is located in Alabama, Arizona, Connecticut, the District of Columbia, Georgia, Iowa, Idaho, Illinois, Indiana, Kansas (other than the Kansas City metro area), Kentucky (other than the Cincinnati metro area), Maryland, Minnesota, Mississippi, Missouri (other than the Kansas City area), Nevada, New Mexico, New York (other than the Buffalo and North Hudson regions), North Carolina, Pennsylvania (other than the Philadelphia Region), South Carolina, South Dakota, Texas, Utah, Vermont, Washington, West Virginia, Wisconsin, or Wyoming. This means that more than 40% of the Medicare beneficiaries in the country will not have an opportunity to receive care from a primary care practice participating in either Primary Care First or Comprehensive Primary Care Plus.

In the eighteen states/regions that are part of the CPC+ demonstration, a primary care practice will only be able to participate in Primary Care First in the first year of the program if the practice is not already participating in CPC+. Since CPC+ accepted essentially all practices in those eighteen states/regions that were interested and qualified, and since the payments under CPC+ would be higher and more predictable than those under Primary Care First, it seems unlikely that many practices from these regions would participate in Primary Care First.

Consequently, most participants in Primary Care First will likely come from just eight states (Alaska, California, Delaware, Florida, Massachusetts, Maine, New Hampshire, and Virginia), and the majority of eligible Medicare beneficiaries would live in either California or Florida. The program will not even be open to every primary care practice in these eight states; practices will only be able to participate in Primary Care First if they have at least 125 attributed Medicare beneficiaries and if they have "experience with value-based payment arrangements or payments based on cost, quality, and/or utilization performance such as shared savings, performance-based incentive payments, and episode-based payments, and/or alternatives to fee-for-service payments such as full or partial capitation."

The Direct Contracting Options Are Not Options for Most Primary Care Practices

Large primary care practices with at least 5,000 beneficiaries would also be eligible to participate in one of the new "Direct Contracting" options in the CMS Primary Cares Initiative as an alternative to participating in Primary Care First. As noted earlier, most counties in the U.S. do not have 5,000 Medicare beneficiaries living in them, so this option would primarily be applicable to practices located in urban areas.

Under the "Professional Population-Based Payment Direct Contracting" option, a participating primary care practice would receive a monthly payment for "enhanced primary care services." The amount of the payment would be set equal to 7% of the total Medicare Part A and Part B spending on the practice's patients. (CMS has not clearly defined whether "enhanced primary care services" involves just Evaluation & Management (E/M) services such as office visits and chronic care management services, or other services that the primary care practice delivers.) Since Medicare Part A & B spending is projected to be approximately $12,500 per beneficiary per year in 2020, 7% of that amount would translate into about $73 per beneficiary per month, which is significantly more than the revenues primary care practices receive today for E/M services and more than what most practices would receive under the basic Primary Care First option.

However, in return for this higher and more flexible payment, a primary care practice participating in the Direct Contracting option would be required to pay CMS for 50% of any increases in total Medicare spending for its attributed patients beyond whatever benchmark spending level CMS establishes. CMS has not defined how it would establish the benchmark spending level in Primary Care First, and while it has said there would be limits on the amount a direct contracting practice would have to repay when total Medicare spending is higher than expected, CMS has not yet defined the specific risk corridors or stop-loss threshold it will use. Since Medicare payments to the primary care practice would only equal 7% of total Medicare spending, if total Medicare spending increased by just 5% more than the expected level, the amount the primary care practice would have to repay could represent more than one-third of the practice's Medicare revenue. It is unlikely that even medium-sized primary care practices would have the financial reserves needed to manage this level of financial risk.

The Direct Contracting options will likely be of interest primarily to the Accountable Care Organizations (ACOs) participating in the downside risk tracks of the Medicare Shared Savings Program (MSSP), since it would enable the physicians in the ACO to be paid in a more flexible way than is possible today, and to health systems or large multi-specialty groups that are not currently participating in MSSP and have significant financial reserves needed to take on this level of financial risk.

Undesirable Impacts of Implementing Primary Care First as it is Currently Designed

Because the current design of Primary Care First uses non-risk adjusted monthly and visit-based payments and bases the performance-based adjustment primarily on the rate of hospital admissions relative to other practices, it could be a very attractive option for primary care practices whose Medicare patients are relatively healthy. If the practice's Medicare patients don't need many office visits and if the visits they do make are for simple issues, a $24 monthly payment combined with a $50 visit fee would result in significantly more revenue for the practice than current E/M fees. Moreover, since those healthy patients likely already have a low rate of hospitalization, the practice would also be likely to receive a high

"performance-based" bonus on top of the monthly and visit-based payments.

On the other hand, if a practice has many low-income Medicare patients who experience frequent acute health problems, the $24 monthly payment and $50 visit fee could generate less revenue that the practice receives today under the traditional fee-for-service system. Moreover, if the patients' acute care problems are severe enough to require inpatient treatment, the practice would be unlikely to qualify for a performance bonus, since the risk adjustment in the hospitalization measure would not account for new or acute illnesses or for other patient characteristics that can result in higher rates of hospitalization. The practice would likely even have difficulty reducing the subset of hospitalizations that were avoidable because it would not receive higher payments to support expanded care management services for its patients. Consequently, the practice would be unlikely to receive a bonus payment and it could even be subject to a penalty. It would not be a wise decision for such a practice to participate in Primary Care First, even though that is exactly the kind of practice that most needs additional support.

If only the practices with relatively healthy, infrequently-hospitalized patients participate in Primary Care First, Medicare spending would increase significantly, since those practices could receive much higher payments than they do today even if there is no further reduction in their already-low rates of hospitalization. This might prompt CMS to try and mandate participation by all primary care practices in order to force practices with high rates of hospitalization to participate. However, mandating participation in a poorly-designed program would likely just accelerate the demise of primary care practices rather than result in greater savings for the Medicare program.

The most undesirable impact of all would be if the primary care practices that do enroll in Primary Care First find that they have to avoid accepting sicker and more complex patients in their practices because the payments are inadequate to support the care needed by those patients. While CMS may have designed Primary Care First to provide a strong financial incentive for primary care practices to reduce hospitalization rates, the design also provides a strong financial incentive for primary care practices to avoid serving patients who have a high risk of hospitalization. The non-risk adjusted payments in Primary Care First also could discourage practices from serving patients who require significant amounts of extra time from practice staff in order to prevent the development of new health problems. If these patients have greater difficulty obtaining primary care services, Medicare spending will likely increase.

While CMS may have designed Primary Care First to provide a strong financial incentive for primary care practices to reduce hospitalization rates, the design also provides a strong financial incentive for primary care practices to avoid serving patients who have a high risk of hospitalization.

Changing Primary Care First So It Provides the Support Small Primary Care Practices Need

Fortunately, it would be relatively easy for the Center for Medicare and Medicaid Innovation (CMMI) to modify the Primary Care First initiative to solve the problems described above. The following nine changes would enable CMMI to create the kind of payment model that smaller primary care practices have been seeking:

1. Pay practices with a monthly per-patient payment in place of all fees for office visits.

Instead of a combination of monthly payments and office visit fees, Primary Care First should pay primary care practices a monthly payment for each enrolled patient, with no separate fees for office visits. This is what was requested by both AAFP and Dr. Antonucci in the payment models they submitted to PTAC and that PTAC recommended that HHS implement. CMMI is already testing a payment model with both monthly payments and fees in Track 2 of CPC+, but it is not testing a monthly payment in place of all fees in any of its other demonstration projects.

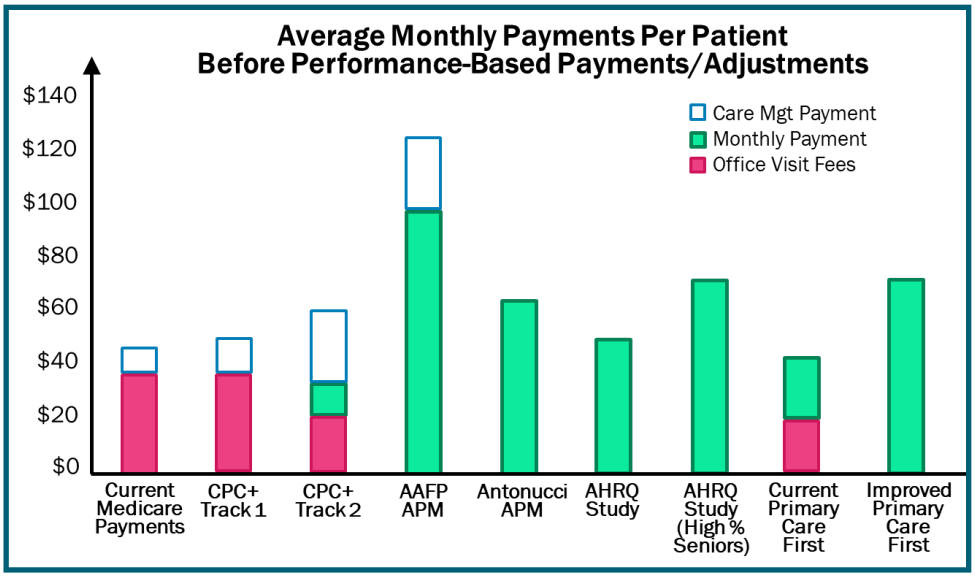
2. Pay a higher monthly amount for a patient who has greater needs.

Under the payment models developed by both the AAFP and Dr. Antonucci, a primary care practice would receive a higher payment for a patient with greater needs. A patient's needs should not be determined by the patient's Hierarchical Condition Category (HCC) score. Instead, it should be based on all of the patient's current health problems and on other factors such as functional limitations that affect the amount of time and types of services the primary care practice will need to deliver in order to properly care for the patient. In CPC+, CMMI requires primary care practices to risk stratify patients, and practices participating in Primary Care First would also be required to do so, so it would be a simple matter to base monthly payment amounts on important clinical characteristics of patients that are not currently captured in Medicare claims data.[33]

3. Set monthly payment amounts at levels adequate to support high-quality primary care services.

There is broad consensus that it is not enough to change the *method* by which primary care practices are paid; the *amount* of money they receive must be significantly higher than it is today. The first-year evaluation of CPC+ reported that most primary care practices felt the payment amounts under CPC+ were not adequate to support the kinds of services they needed to perform, so the payments under Primary Care First should be higher than the CPC+ payment amounts, not less.[34]

HHS funded a detailed study of the staffing required to deliver high-quality primary care services through the Agency for Healthcare Research and Quality (AHRQ).[35]



The study found that a primary care practice would need to be paid at least $45 per patient per month for an average patient population, a higher amount ($46) if the practice were located in a rural area, an even higher amount ($56) if its patients had high social needs, and $64 per patient per month if the practice had a higher-than-average population of seniors. These estimates were calculated in 2015 dollars, so the inflation-adjusted amounts in 2020 would be approximately $50, $51, $62, and $71 respectively. These amounts assume the practice is receiving the same payments from all payers for all patients in the practice, so a practice would need to receive Medicare payments at least as high as these amounts in order for the overall revenues to the practice to cover the costs the studies found would be necessary to deliver high-quality care.

In the two proposals recommended by PTAC, the AAFP recommended that primary care practices receive payments equal to 12% of total Medicare spending; this would translate into about $125 per patient per month. Dr. Antonucci recommended that small and rural practices receive a $60 per month payment for low-to-medium risk patients and $90 per month for high risk patients. In the Comprehensive Primary Care Plus program, Track 1 practices with an average risk population receive about $50 per patient each month and Track 2 practices receive about $62.

Consequently, the monthly payment under Primary Care First should be no less than $65 per patient in 2020, and ideally even higher. The monthly payment amounts for patients with more complex needs should be higher than this average amount.[36] Payments should be increased annually based on inflation in order to ensure the primary care practice receives adequate revenues to cover increases in costs.

4. Begin paying monthly payments immediately when a patient enrolls for care in the primary care practice.

Rather than forcing patients to go to a website to designate the primary care practice as their primary care provider, and then forcing the practice to wait up to 6 months to receive monthly payments for that patient, a patient should be able to sign a form designating the practice as their primary care provider, and the primary care practice should be able to immediately begin receiving monthly payments for that patient.

CMS already does this for Chronic Care Management (CCM) payments under the Medicare Physician Fee Schedule – as soon as a patient consents to receive CCM services, the physician practice can begin delivering the services and receiving payment for them.[37] The practice is required to inform the patient that only one practitioner can furnish and be paid for CCM services during a calendar month and the patient has the right to stop services at any time (with termination effective at the end of the month). Patient consent is only required once before services begin or if the patient wants to begin receiving services from a different provider. A similar approach could be used to trigger the payments under Primary Care First.

5. Create billing codes so that primary care practices can classify patients appropriately and receive timely monthly payments for each patient.

The most efficient way to implement all of the above changes would be to allow the primary care practice to submit a newly-created billing code each month for each patient who is receiving Primary Care First services from the practice. By submitting the billing code, the practice would be proactively affirming that the patient is receiving appropriate primary care services from the practice during that month. This would allow immediate changes in payments for new patients who join the practice and for patients who leave the practice, rather than waiting for 6 months to 2 years for adjustments to be made through CMS attribution and alignment processes.

A different billing code should be created for each category of higher-risk patients. In order to submit one of these billing codes, the primary care practice would need to document that the patient had the characteristics associated with the category. This would enable defining

the categories using clinical characteristics of patients, not just the diagnosis codes currently used in claims data.[38] Separate billing codes based on a patient's risk category would also allow a practice to receive higher payments immediately when a patient developed a new chronic condition, rather than waiting for a year or more for CMS to calculate a new risk score for the patient.

CMS already uses these types of billing codes for the monthly payments it makes to primary care practices for Chronic Care Management (CCM) services, and there are two different codes to distinguish patients with different levels of complexity: CPT 99490 for regular CCM services and CPT 99487 for "complex" CCM services. CMS also created a new billing code (G9678) to enable oncology practices participating in the CMMI Oncology Care Model to bill for Monthly Enhanced Oncology Services (MEOS) Payments. Similar mechanisms could be used to implement new billing codes for payments to primary care practices under Primary Care First.

6. Evaluate performance using patient-centered outcome measures with achievable performance targets.

Primary care practices clearly agree that in return for receiving larger and more flexible payments, they can and should take greater accountability for delivering high-quality care to their patients and for reducing avoidable services and spending. Although both the AAFP and Antonucci proposals recommended by PTAC include performance-based payment components, neither proposed evaluating performance using only a single measure such as the total hospital admission rate used in the current version of Primary Care First. The AAFP model proposed to use a combination of quality measures and utilization measures similar to the approach currently being used in CPC+, but with a broader range of quality measures that also reflect the needs of patients who have health issues other than diabetes and hypertension. Dr. Antonucci recommended moving away from traditional quality measures altogether and using a patient-reported outcome measure designed to ensure that the primary care practice is addressing what matters most to each individual patient regardless of the specific types of health problems the patient has.

A revised version of Primary Care First would better ensure high-quality care for all patients in a practice while still encouraging savings for Medicare by using patient-centered measures defined as follows:

Accountability for Avoidable Hospitalizations

- Measure the rate of *potentially avoidable* hospitalizations among the practice's patients, rather than the rate of *total* hospitalizations. Definitions of avoidable hospitalizations are available and could easily be incorporated into a performance measure.[39] For example, a hospitalization for an exacerbation of COPD is potentially avoidable, whereas a hospitalization for an auto accident or cancer surgery is not.
- Risk-adjust or risk-stratify the avoidable hospitalization measure based on patient characteristics that are known to affect the risk of hospitalization but cannot easily be modified by a primary care practice. Many of these characteristics will already be identified and documented by the practice in order to bill for the stratified payments. For example, COPD patients who have more severe cases of COPD or who cannot afford the cost-sharing for the bronchodilators needed to control COPD exacerbations would be expected to have more hospitalizations for exacerbations than other patients with COPD, so a primary care practice should not be penalized for a higher rate of hospitalizations if it has more such patients than others.
- Set a target range for the risk-adjusted avoidable hospitalization rate based on what is known to be achievable by adequately-resourced primary care practices, and reward or penalize the practice only if it falls outside of that range. The range should be large enough to avoid rewarding or penalizing a practice based on typical month-to-month and year-to-year random variations in avoidable hospitalization rates. The types of decile-based performance ranges CMS currently plans to use in Primary Care First would be too small to reliably measure the performance of small practices.

Accountability for Quality and Outcomes

- Initially, measure the quality of care using a group of the standard primary care quality measures that are used in the Merit-Based Incentive Payment System (MIPS), similar to the payment model developed by AAFP, and set performance targets based on recent MIPS benchmarks. This would allow participating practices to easily set improvement goals and track their performance, and it would allow CMS to ensure that quality is being maintained or improved.
- In addition, pay practices more if they are willing to begin collecting patient-reported outcome measures, such as the "How's Your Health" measure used in the payment model developed by Dr. Antonucci. Collecting these data will require extra time and effort by primary care practices, and they will need additional resources to enable them to do so. In the Comprehensive Care for Joint Replacement (CJR) payment model, CMMI allows hospitals to retain more savings if they collect and report outcome measures.[40]
- Once a feasible strategy for collecting patient-reported outcomes has been developed and sufficient outcome data are available to establish performance targets, begin transitioning the performance measurement for Primary Care First practices from traditional quality measures to the patient-reported outcome measures.

7. Establish performance-based rewards and penalties that create manageable levels of financial risk for small primary care practices.

Both the AAFP and Antonucci proposals recommended by PTAC proposed to adjust payment amounts based on a practice's performance. However, neither proposal recommended that payments to primary care practices should vary by as much as 60% as in the current version of Primary Care First. In the AAFP payment model, practices could have their payments reduced by up to $2.50-$4.00 per patient per month if they failed to meet prede-

fined performance benchmarks for quality and utilization. In the payment model developed by Dr. Antonucci, 15% of the payments would be withheld and the practice would only receive the withheld amount if it achieved predefined quality and utilization benchmarks.

Moreover, both the AAFP and Antonucci models, as well as the existing CMS CPC+ model, provide higher payments to practices so they can improve outcomes for patients, rather than making higher payments completely contingent on performance as in the current design of Primary Care First. Because payments would be higher under both the AAFP and Antonucci payment models than they are today, payment adjustments could create significant financial rewards and penalties for a practice based on its performance without placing the practice at risk of bankruptcy if it fails to perform well. Similarly, in the current CMS CPC+ models, primary care practices receive higher revenues through significant Care Management Fees regardless of their performance; only the Performance-Based Payment, equal to about 5-7% of their revenues, is contingent on performance.

A revised version of Primary Care First should follow a similar approach. As discussed earlier, it should provide significantly higher payments to primary care practices to enable them to deliver high-quality care to their patients. A performance-based component should then be added with the following characteristics:

- the desirable target range for each performance measure (i.e., the avoidable hospitalization rate and/or the quality/outcome measures) should be defined in advance, so primary care practices know what standard they will need to meet in order to receive monthly payments at the expected level. A practice's performance should not be based on what other practices achieve during the same year.
- the monthly payment to a practice should be increased or decreased by a predefined amount if its performance falls outside the predefined target range. If every primary care practice performs better than the target range, every primary care practice should be rewarded for doing so. Primary care practices could still compete with each other and be rewarded for doing better than other practices, rather than making the amount of the reward for each practice depend on how many other practices did better or worse.
- the total adjustment to the monthly payment based on all aspects of performance should be no more than 15% of base payment amounts, assuming that the base payment amounts for the practice have been increased to levels much higher than current Medicare payments.
- the payment adjustments should be phased in over a several year period, to reflect the fact that even if a primary care practice immediately begins changing the way it delivers care to patients, it will take time for the patients' health status to improve and for the patients to learn and successfully implement better approaches to self-management in order to reduce the risk of avoidable hospitalizations.

8. Create a complementary payment model to support home-based palliative care for seriously ill patients.

Multiple studies and demonstration projects have shown that providing home-based palliative care services to patients with serious, potentially life-limiting illnesses can both improve their quality of life and reduce Medicare spending by significantly reducing the frequency with which they visit an emergency department, are admitted to the hospital, and receive other expensive services. However, Medicare does not currently pay for home-based palliative care services other than for patients on hospice, so patients who are still being treated for their illnesses cannot receive these desirable and cost-effective complementary services.

Both the American Academy of Hospice and Palliative Medicine (AAHPM)[41] and the Coalition to Transform Advanced Care (CTAC)[42] developed payment models designed to solve this problem, and PTAC recommended that HHS implement both models.[43] AAHPM recommended payments of $400 per month for advanced illness patients of moderate complexity and $650 per month for high complexity patients, and CTAC recommended payments of between $400 per month and $650 per month based on the palliative care provider's performance in reducing total spending while the patient is receiving services. Based on the proposals from AAHPM and CTAC, it seems clear that monthly payments for palliative care services will need to be at least $400 for most patients and even higher for more complex patients in order to cover the costs of delivering high-quality services and to ensure that patients with the most complex needs can receive the services they need.

These payments should be provided to palliative care providers separately from the payments used to support primary care services. Although a large primary care practice may have enough advanced illness patients to enable the practice to deliver home-based palliative care services cost-effectively, a small primary care practice will not. A palliative care provider will also need to have a sufficient number of advanced illness patients in order to deliver palliative care services cost-effectively. In rural areas and other communities served by small primary care practices, a palliative care provider will need to deliver services to patients from multiple primary care practices, potentially across a large geographic area, in order to have enough patients to allow home-based services to be delivered cost-effectively. Creating a separate monthly payment for palliative care services would support both scenarios, enabling a small practice to request services for an advanced illness patient from a separate palliative care provider, and enabling a large practice to deliver the services itself if it wished to do so.

Patients with advanced illness who need home-based palliative care services in addition to traditional primary care services can be identified using the criteria developed by AAHPM and CTAC in the payment models they developed. This would be preferable to the claims-based methodology CMS has proposed to use in the Serious Illness option for Primary Care First, since claims data do not contain information on some of the most important clinical criteria needed to identify appropriate patients.

9. *Allow primary care practices in all parts of the country to participate in the revised Primary Care First program.*

Every Medicare beneficiary deserves to receive high quality primary care services, and every beneficiary with a serious illness deserves to receive palliative care services. While there are differences of opinion about the best way to structure payments for these services, there is broad consensus that the current payments are inadequate and need to be increased significantly. It would be inappropriate to prevent more than 40% of the Medicare beneficiaries from receiving better primary care services for another five years while CMMI tests additional payment model options in only eight states. Consequently, Primary Care First should be expanded so that every primary care practice in every state has the opportunity to participate, and so that palliative care services can be delivered in every community.

The Goal of Primary Care is to Improve Patients' Health, Not Just to Save Money for Medicare

Higher and more flexible payments for primary care will enable delivery of better primary care services. This will likely result in fewer avoidable hospitalizations, unnecessary tests, and inappropriate referrals to specialists, which in turn will produce significant savings for Medicare. However, it may be unrealistic to expect these savings to fully offset the cost of the higher payments needed to adequately support primary care, much less to achieve net savings overall, during the 5-year time period typically used in CMMI evaluations.

Net savings in the early years of an improved Primary Care First model will likely be low, not because of a lack of adequate "risk" for the practices, but because most of the benefits of good primary care will not appear immediately. Efforts to place more financial risk on primary care practices are more likely to accelerate the loss of primary care providers than to achieve greater savings for Medicare. In fact, measuring savings based on changes from *current* levels of Medicare spending presumes that primary care practices will be *able to continue to deliver current levels of services if payments are not increased to adequate levels*. The correct "benchmark" for savings should not be the current level of total spending, but the higher level of Medicare spending that would likely result if access to high-quality primary care services continues to decline. Paying more to preserve primary care practices will be more likely to show that net savings for Medicare have been achieved if the "counterfactual" is defined properly.

Because of the need to take a longer-term view of the value of primary care, the Center for Medicare and Medicaid Innovation (CMMI) may not be the appropriate mechanism for successfully addressing the problems facing primary care. Congressional action will likely be needed to create a truly effective primary care payment system.

Because of the need to take a longer-term view of the value of primary care, the Center for Medicare and Medicaid Innovation (CMMI) may not be the appropriate mechanism for successfully addressing the problems facing primary care. By statute, its authority is limited to "testing models" that address deficits in care, not fundamentally restructuring Medicare payment systems for all primary care physicians or even improving the health of Medicare beneficiaries. The need to conduct formal evaluations of payment models has limited the number of states and regions where CMMI can implement changes and has led it to threaten the use of narrowly-defined "mandatory" demonstrations instead of encouraging innovation through multiple, voluntary approaches. Moreover, although CMMI is explicitly authorized to undertake demonstrations that are not initially budget neutral, Congress required it to focus on projects that would reduce Medicare spending, and CMMI is prohibited from continuing a demonstration unless there is reason to believe that spending will not increase. The experience to date suggests that the reforms needed in primary care payment may not meet those criteria.[44]

CMMI is not the only vehicle for changing the way Medicare pays primary care practices. CMS has the authority to create new types of payments for every primary care practice in the country, and over the past several years, it has created several new fees to support additional services by primary care practices. Moreover, CMS can make sweeping changes quickly when it chooses to do so -- for example, the physician fee schedule regulation that CMS proposed in 2018 would have completely restructured payments for office visits to all types of physicians in less than a year. However, CMS is also constrained by budget neutrality rules that are even more narrowly defined than those facing CMMI, since CMS cannot consider savings in hospital spending as offsets for higher payments to primary care physicians.

Because of these constraints, it seems increasingly likely that Congressional action will be needed to create a truly effective primary care payment system. The biggest benefits of primary care will be seen beyond the five-year time horizon used in CMMI demonstration projects, through slowing the progression of chronic disease and even preventing some diseases from occurring at all, not just trying to avoid hospitalizations for those who already have such conditions. Moreover, Medicare will save even more money if individuals are healthier when they first become eligible for Medicare, and that will only occur if more people receive good primary care long before they are 65. Since most primary care practices serve both Medicare beneficiaries and younger individuals, better payments for primary care from Medicare will also enable primary care practices to deliver more and better services to younger patients, increasing the long-run return on investment for the Medicare program. However, only Congress can authorize making investments designed to achieve these longer-run benefits. Consequently, in addition to revising Primary Care First to make it as successful as possible within current statutory constraints, CMS should ask Congress for the authority to create the kind of primary care payment system that the country truly needs.

APPENDIX

COMPARISON OF CURRENT AND PROPOSED CMS PRIMARY CARE MODELS TO PRIMARY CARE PAYMENT MODELS RECOMMENDED BY PTAC

Dimension	CPC+	AAFP APM	Antonucci APM	Primary Care First
Payments for Office Visits	Payments for office visits are unchanged in Track 1. Payments for office visits continue at reduced amounts in Track 2. Standard office visit payments continue for all unattributed patients.	No separate payments for office visits for enrolled patients. Standard office visit payments continue for patients who are not enrolled or attributed.	No separate payments for office visits for enrolled patients. Standard office visit payments continue for patients who are not enrolled or attributed.	$50 payment for each office visit, regardless of length, in place of current office visit fees for attributed patients. Standard office visit payments continue for all unattributed patients.
New Payments for Evaluation & Management (E/M) Services	Track 2 practices receive a quarterly payment for each attributed patient based on a fraction of past average office visit revenues in the practice. There is no difference in the quarterly payment based on individual patient needs.	Monthly payment in place of office visit fees for enrolled patients. Higher monthly payment for each patient with higher needs.	Monthly payment in place of office visit fees and most other services for enrolled patients. Higher monthly payment for each patient with higher needs.	Monthly payment for each attributed patient. No difference in payment based on individual patient needs. Monthly payment for all patients is higher if the average risk score for all patients in the practice is high.
Payments for Care Management Services	Monthly payment for each attributed patient. Higher payment for each patient with higher needs.	Monthly payment for each enrolled patient. Higher payment for each patient with higher needs.	No separate payment for care management services.	No separate payment for care management services.
Performance-Based Payments	Additional monthly payment of $2.50 (in Track 1) or $4.00 (in Track 2) per attributed patient is paid in advance, but is re-couped if performance on quality and utilization measures is poor.	Additional monthly payment per enrolled patient is paid in advance, but is recouped based on performance on quality and utilization measures.	15% of standard monthly payments is withheld and then paid if the performance standard on the outcome measure is met.	Payments are increased up to 50% based on the rate of hospitalizations relative to other practices and based on improvements in hospitaliza-tion rates if performance standards on quality measures are also achieved. Payments are reduced by 10% if quality performance is low or if the hospitalization rate is high.

(CONTINUED)

COMPARISON OF CURRENT AND PROPOSED CMS PRIMARY CARE MODELS TO PRIMARY CARE PAYMENT MODELS RECOMMENDED BY PTAC (Continued)

Dimension	CPC+	AAFP APM	Antonucci APM	Primary Care First
Performance Measures	MIPS quality and patient experience measures. Two utilization measures (ED visits and total hospitalization rate).	MIPS quality and patient experience measures similar to CPC+. Utilization measures similar to CPC+.	Patient-reported outcomes.	All-cause hospitalization rate. Five quality and patient experience measures for lower-risk patients; Three measures for higher-risk patients.
Patient Eligibility	Patients are attributed to the practice based on the proportion of visits the patient made to the primary care practice over the prior two years. Patients can voluntarily "align" with the practice by designating the practice on the CMS website.	Patients could explicitly designate the practice as their primary care provider. Patients who do not explicitly designate the practice could still be assigned based on where visits have been made in the past.	Patients could explicitly designate the practice as their primary care provider. Patients who do not explicitly designate the practice could still be assigned based on where visits have been made in the past.	Patients are attributed to the practice based on the proportion of visits the patient made to the primary care practice over the prior two years. Patients can voluntarily "align" with the practice by designating the practice on the CMS website.
Method of Measuring Differences in Patient Needs	CMS Hierarchical Condition Categories (CMS-HCC).	The Minnesota Complexity Assessment Model.	The "What Matters Index" based on the How's Your Health patient-reported outcomes tool.	CMS Hierarchical Condition Categories.
Practice Eligibility	Only open to practices located in 18 regions.	Open to practices in all states.	Open to practices in all states.	Only open to practices in Alaska, California, Delaware, Florida, Maine, Massachusetts, New Hampshire and Virginia, and to practices located in the 18 CPC+ regions. Practices must have "experience with value-based payment arrangements." Practices must have at least 125 Medicare beneficiaries.

ENDNOTES

1. Association of American Medical Colleges. *The Complexities of Physician Supply and Demand: Projections from 2017 to 2032* (April 2019)
2. Bodenheimer T, Sinsky C. "From Triple to Quadruple Aim: Care of the Patient Requires Care of the Provider," *Annals of Family Medicine* 12(6): 573-576 (November/December 2014)
3. Dalen JE, Ryan KJ, Alpert JS. "Where Have the Generalists Gone? They Became Specialists, Then Subspecialists," *The American Journal of Medicine* 130(7):766-768 (July 2017)
4. Bodenheimer T, Pham HH. "Primary Care: Current Problems and Proposed Solutions," *Health Affairs* 29(5): 799-805 (May 2010).
5. U.S. Department of Health and Human Services. "HHS to Deliver Value-Based Transformation in Primary Care: The CMS Primary Cares Initiative to Empower Patients and Providers to Drive Better Value and Results" (April 22, 2019). Available at: https://www.hhs.gov/about/news/2019/04/22/hhs-deliver-value-based-transformation-primary-care.html
6. Information on Comprehensive Primary Care Plus is available at https://innovation.cms.gov/initiatives/comprehensive-primary-care-plus/
7. The details that have been made available about the Primary Care First options are posted on the CMS website at https://innovation.cms.gov/initiatives/primary-care-first-model-options/ and the details about the Direct Contracting Model options are posted at https://innovation.cms.gov/initiatives/direct-contracting-model-options/ .
8. American Academy of Family Physicians, *Advanced Primary Care: A Foundational Alternative Payment Model (APC-APM) for Delivering Patient-Centered, Longitudinal, and Coordinated Care* (April 14, 2017). Available at https://aspe.hhs.gov/system/files/pdf/255906/AAFP.pdf
9. Antonucci J. *An Innovative Model for Primary Care Office Payment* (March 18, 2018). Available at https://aspe.hhs.gov/system/files/pdf/255906/ProposalAntonucci.pdf
10. As part of the Medicare and CHIP Reauthorization Act of 2015 (MACRA), Congress created the Physician-Focused Payment Model Technical Advisory Committee (PTAC) to review proposals for physician-focused payment models submitted by individuals and stakeholder entities and to make recommendations to the Secretary of Health and Human Services as to whether the proposals meet criteria for such payment models that have been established by HHS in regulations. The eleven members of PTAC are appointed by the Comptroller General of the United States. More information about PTAC is available at https://aspe.hhs.gov/ptac-physician-focused-payment-model-technical-advisory-committee
11. The PTAC comments and recommendation regarding the AAFP proposal were submitted to the Secretary of Health and Human Services on February 28, 2018 and are available at https://aspe.hhs.gov/system/files/pdf/255906/PTACRecommendationsCommentsAAFP.pdf. The PTAC comments and recommendation regarding the Antonucci proposal were submitted on October 20, 2018 and are available at https://aspe.hhs.gov/system/files/pdf/255726/ReportToTheSecretary_Antonucci_10.20.18.pdf
12. Goroll AH, Berenson RA, Schoenbaum SC, Gardner LB. "Fundamental Reform of Payment for Adult Primary Care: Comprehensive Payment for Comprehensive Care," *Journal of General Internal Medicine* 22(3): 410-415 (March 2007).
13. In 2016, there were 1,805 counties in the U.S. that had fewer than 5,000 Medicare Fee for Service beneficiaries living in them; the remaining 1,340 counties in the country had 5,000 or more. 405 counties had fewer than 1,000 Medicare FFS beneficiaries.
14. In 2019, Medicare pays primary care physicians between $46.49 and $209.75 for an office visit with a new patient and between $23.07 and $147.76 for an office visit with an established patient. (Practices in high cost-of-living areas receive higher payment amounts for the same services.) Most office visits are Level 3 and Level 4 visits with established patients; the national payment amounts for these visits are $75.32 and $110.28. Based on the overall frequency of the different types of visits with family physicians, the average payment for an office visit in 2019 will be about $95.
15. The first-year evaluation of the Comprehensive Primary Care Plus demonstration reported that in 2017, Medicare beneficiaries in CPC+ practices had an average of 4.5-4.6 primary care office visits per year. (Mathematica Policy Research. *Independent Evaluation of Comprehensive Primary Care Plus (CPC+): First Annual Report* (April 2019), available at https://downloads.cms.gov/files/cmmi/cpcplus-first-ann-rpt.pdf.) Assuming a similar average of 4.5 visits per year, a practice participating in Primary Care First would receive an average of $18.75 per patient per month from the $50 per office visit fees and an additional $24 per patient per month from the professional population-based payment, for a total of $42.75 per patient per month. 44% of the total amount would come from the office visit fees. If patients in Primary Care First only made 3 office visits per year on average, the primary care practice would only receive 34% of its revenues from office visits, but it would also receive 15% less revenue in total with the same number of patients.
16. In the Comprehensive Primary Care Plus demonstration project, a Medicare beneficiary must take the following ten steps in order to voluntarily align with a primary care practice:
(1) Create an account on MyMedicare.gov;
(2) Log in to the account;
(3) Select the "My Health" tab and select "Providers" from the drop-down menu;
(4) Select "Physicians & Other Clinicians" and then select the box "Add a Clinician or Group Practice," indicating that pop-ups are allowed if this request is displayed;
(5) Under "Find Medicare physicians and other clinicians," type the primary clinician's zip code and last name;
(6) Select the clinician from the drop-down menu and click Search;
(7) Select "Add to Favorites" in the top right corner of the screen;
(8) On the next page, select the correct address for the clinician;
(9) At the bottom of the screen, under the header "Add as

Your Primary Clinician," check the box labeled "Make this my primary clinician" and click "Add to Favorites"; (10) If a green pop-up box indicates that the physician has been added to the beneficiary's favorites list, click on MyMedicare.gov on top of the browser and then click the box "Update Provider Data."

If this is successfully done, the beneficiary will appear on the Beneficiary Attestation List, and CMS will assign the beneficiary to the practice two calendar quarters later. For example, if the beneficiary completes the voluntary alignment process between April 1 and June 30 of 2019, they will be assigned to the practice beginning in October 2019. (Center for Medicare and Medicaid Innovation. *CPC+ Payment and Attribution Methodologies for Program Year 2019, Version 2* (February 21, 2019). Available at https://innovation.cms.gov/Files/x/cpcplus-methodology-py19.pdf.)

17. The evaluation of the CMS Comprehensive Primary Care (CPC) demonstration, which preceded the current CPC+ demonstration, found that out of the 3.05 million patients served by CPC practices, only 320,713 were attributed Medicare beneficiaries and thereby eligible for the additional Medicare payments available under CPC, and only 805,980 were patients attributed by other payers and eligible for different payments from those payers. 63% of the total patients served by the practices were not "attributed" to the practices and so the practices received only traditional fee-for-service payments for those patients. Mathematica Policy Research, *Evaluation of the Comprehensive Primary Care Initiative: Fourth Annual Report* (May 2018). Based on the information reported in the first-year evaluation of the CPC+ demonstration, it appears that an even larger percentage of the patients who are receiving services from CPC+ practices are not being attributed to the practices by Medicare or other payers, and therefore the practices are not receiving different payments for those patients.

18. A patient's HCC score is based only on how many different chronic condition diagnoses are recorded in claims data for the patient, not how severe the conditions are, and not on any acute conditions the patient is experiencing (for example, a patient with pneumococcal pneumonia does not receive a higher HCC score). Moreover, HCC scores are only based on the chronic conditions diagnosed two years earlier, not on any newly diagnosed conditions that a primary care practice would need to address in the current year. In the CPC+ initiative, CMS asks practices to risk stratify their patients, and most practices assign risk levels to patients using clinical factors other than the information used in HCC scores. Mathematica Policy Research. *Independent Evaluation of Comprehensive Primary Care Plus (CPC+): First Annual Report* (April 2019), available at https://downloads.cms.gov/files/cmmi/cpcplus-first-ann-rpt.pdf.)

19. American Academy of Hospice and Palliative Medicine. *Payment Reforms to Improve Care for Patients With Serious Illness* (August 2017). Available at https://aspe.hhs.gov/system/files/pdf/255906/ProposalAAHPM.pdf

20. Coalition to Transform Advanced Care. *Advanced Care Model (ACM) Service Delivery and Advanced Alternative Payment Model* (October 2017). Available at https://aspe.hhs.gov/system/files/pdf/253406/ACM.pdf

21. In 2019, a primary care practice with an average risk group of Medicare patients will likely receive an average of about $35 per beneficiary per month (PBPM) from Medicare E/M fees for office visits, based on an average of 4.5 visits per beneficiary per year and an average office visit payment of $93 for established patients and $128 for new patients at 2019 Medicare Physician Fee Schedule rates. A practice can also bill an additional $42 per month for Chronic Care Management (CCM) services to patients who have two or more chronic diseases. Although many practices do not bill for this service for all eligible patients because of administrative burdens in doing so and the requirement for patient cost-sharing, a practice that bills for this payment for 25% of its patients would increase its total average PBPM payment for the two sets of E/M services to $46. Because patients are required to pay 20% co-insurance for most of these visits, the practice would receive about $37 PBPM from CMS and the remaining $9 PBPM from the patient.

    Under the Primary Care First model, a practice with an average risk patient population would only receive $24 PBPM from CMS through the Professional Population-Based Payment, and there would be no patient contribution for these payments. The practice could no longer bill for E/M office visits or CCM payments if it receives the $24 PBPM. The practice would be eligible for an additional $50 fee for each office visit made by the patients; if patients continue visiting practices at the rate of 4.5 visits per year, the practice would receive an additional $18.75 PBPM for office visits. If the practice reduced the average number of office visits to 3 per year by delivering care in different ways, the practice's office fee revenue would decrease to $12.50 PBPM.

    As a result, the combination of PBPM payments and office visit fees under Primary Care First would generate a total of $36.50 - $42.75 PBPM for the practice, compared to $35.00 - $46.00 PBPM under the current Medicare Physician Fee Schedule.

22. Under the current design of Primary Care First, CMS has indicated that participating practices would only be eligible for the "Cohort Adjustment" if the total rate of hospitalizations for their patients is below the median level for other participating practices, and they would only be eligible for the maximum Cohort Adjustment of 34% if they are among the practices with the lowest 20% of hospitalization rates among those practices with below-median rates, i.e., only practices in the lowest decile of hospitalization rates among the participating practices would receive the maximum increase. Practices with hospitalization rates just below the median would only qualify for a 6.5% adjustment. The maximum 34% adjustment under this component would represent 2/3 of the total maximum 50% performance-based adjustment possible, and it would only be available to 10% of practices.

23. Under the "Continuous Improvement Adjustment," practices whose improvement performance is below the 60th percentile would receive a 3.5% increase in payments. Only 10% of practices would be eligible for the maximum 16% increase on this component, and they may or may not be the same as the 10% of practices who could receive the maximum 34% increase under the Cohort Adjustment.

24. Data released by CMS indicate that on average, in 2017, CPC+ practices were only able to retain 41.5% of the Utilization Component of their Performance Based Incentive Payment (PBIP) that was based on emergency department visits and hospital admissions. Fewer than 3% retained the full amount of the Utilization Component, and 33% had to return the entire amount to CMS. Centers for Medicare and Medicaid Services, *2017 CPC+ Quality and Utilization Performance Results*. Available at https://innovation.cms.gov/Files/worksheets/CPC_PY2017QualityUtilizationPerformanceResults.xlsx .

25. Joynt KE, Gawande AA, Orav EJ, Jha AK. "Contribution of Preventable Acute Care Spending to Total Spending for High-Cost Medicare Patients," *JAMA* 309(24):2572-2578 (2013).

26. Wadhera RK et al. "Association of the Hospital Readmissions Reduction Program With Mortality Among Medicare Beneficiaries Hospitalized for Heart Failure, Acute Myocar-

dial Infarction, and Pneumonia." *JAMA* 320(24):2542-2552 (2018)

27. As noted earlier, in both the Comprehensive Primary Care and the Comprehensive Primary Care Plus demonstrations, a majority of primary care practices' patients were not attributed to them. Studies of Accountable Care Organizations in the Medicare Shared Savings Program, which uses similar attribution methods, have found that many patients are not attributed to the providers who serve them. See, for example, Ouayogodé MH et al. "Forgotten Patients: ACO Attribution Omits Low-Service Users and the Dying." *American Journal of Managed Care* 24(7): e207-e215 (2018).
28. Center for Medicare and Medicaid Innovation. *CPC+ Payment and Attribution Methodologies for Program Year 2019, Version 2* (February 21, 2019).
29. Glazier RH et al. "Do Incentive Payments Reward the Wrong Providers? A Study of Primary Care Reform in Ontario, Canada" *Health Affairs* 38(4):624-632 (2019).
30. Johnston KJ, Joynt Maddox KE. "The Role of Social, Cognitive, and Functional Risk Factors in Medicare Spending for Dual and Nondual Enrollees." *Health Affairs* 38(4):569-576 (2019).
31. In the Cohort Adjustment component of the Performance-Based Payment, practices with hospital admission rates that are above the median for other practices would receive a 0% adjustment. If the practice is in the 41%-50% decile, it would receive a 6.5% increase; if it is in the 31%-40% decile, it would receive a 13% increase; in the 21%-30% decile, a 20% increase; in the 11-20% decile, a 27% increase, and in the lowest decile, a 34% increase. Consequently, if the practice is below the median, its payment will differ by 7% depending on its performance decile. For the Continuous Improvement Adjustment component, payments would differ by 3-3.5% depending on the decile of performance below the median.
32. The first-year evaluation of the CPC+ demonstration reported that the total hospitalization rate for the Medicare fee-for-service beneficiaries in the CPC+ practices in 2017 was 285.8 admissions per 1,000 beneficiaries, and the rate for comparison practices was 283.6 per thousand. (Mathematica Policy Research. *Independent Evaluation of Comprehensive Primary Care Plus (CPC+): First Annual Report.*) For a practice with 125 attributed/aligned Medicare beneficiaries (the minimum required to participate in Primary Care First), this would represent about 36 total hospital admissions during the course of the year, or about 9 admissions per calendar quarter. Under Primary Care First, the Performance-Based Adjustment is based on the deciles of admission rates across participating patients. Since the deciles of admission rates near the median differ by about 10-20 admissions per thousand, this would represent fewer than 3 admissions per year for a practice with 125 beneficiaries, or less than 1 admission per calendar quarter. In other words, one more or one fewer hospital admission for the patients in a very small practice could result in the practice being assigned to a different performance decile, and thereby subject to a 7% increase or decrease in its monthly payments. Even for a larger practice with 500 beneficiaries, 2-3 more or fewer admissions during a quarter could result in a change in its payment.
33. Mathematica Policy Research. *Independent Evaluation of Comprehensive Primary Care Plus (CPC+): First Annual Report* (April 2019)
34. Mathematica Policy Research. *Independent Evaluation of Comprehensive Primary Care Plus (CPC+): First Annual Report* (April 2019)
35. Meyers DM et al. "Workforce Configurations to Provide High-Quality, Comprehensive Primary Care: A Mixed-Method Exploration of Staffing for Four Types of Primary Care Practices," *Journal of General Internal Medicine* 33 (1):1774-1779 (July 2018).
36. Under Primary Care First, practices would be paid $100 and $175 per month for each patient if the overall average risk score for all patients in the practice is high, so presumably the payments for individual patients with high risk levels should be at least $100 per month.
37. Centers for Medicare and Medicaid Services. *Chronic Care Management Services*. (December 2016) Available at https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/chroniccaremanagement.pdf.
38. Documenting the patient characteristics for these new billing codes would be analogous to the current requirement for a practice to document why it is billing for a higher-level Evaluation & Management (E/M) code for an office visit, except that the documentation required for the new billing codes would be clinically relevant to the patient's care, whereas both physicians and CMS agree that the documentation currently required for E/M codes is not clinically relevant and is administratively burdensome.
39. A decade ago, the Health Care Incentives Improvement Institute developed definitions of "potentially avoidable complications" associated with particular procedures and hospitalizations and with chronic disease management. de Brantes F, D'Andrea G, Rosenthal MB. "Should Healthcare Come With a Warranty?" *Health Affairs* 28(4): w678-w687 (2009). Several measures based on these definitions of potentially avoidable complications have been endorsed by the National Quality Forum (Measures #0704 - Proportion of patients hospitalized with AMI that have a potentially avoidable complication, #0705 - Proportion of patients hospitalized with stroke that have a potentially avoidable complication, #0708 - Proportion of patients hospitalized with pneumonia that have a potentially avoidable complication, and #0709 - Proportion of patients with a chronic condition that have a potentially avoidable complication during a calendar year. Available at http://www.qualityforum.org.) 3M Information Systems has developed software to identify a series of "Potentially Preventable Events," including "Potentially Preventable (Initial) Hospital Admissions," that are used by a number of states and health plans. Goldfield N, Kelly WP, Patel K. "Potentially Preventable Events: An Actionable Set of Measures for Linking Quality Improvement and Cost Savings." *Quality Management in Health Care* 21(4):213-219 (October-December 2012).
40. In the Comprehensive Care for Joint Replacement (CJR) demonstration, the quality scores for participating hospitals are increased by 10% if they submit data on patient-reported outcomes and patient risk factors that are not included in claims data. The risk factors represent information such as body mass index, pre-operative use of narcotics, and level of pain, and the outcomes measured include pain and functionality. Centers for Medicare and Medicaid Services. *Overview of CJR Quality Measures, Composite Quality Score, and Pay-for-Performance Methodology*. Available at https://innovation.cms.gov/Files/x/cjr-qualsup.pdf.
41. American Academy of Hospice and Palliative Medicine. *Payment Reforms to Improve Care for Patients With Serious Illness* (August 2017). Available at https://aspe.hhs.gov/system/files/pdf/255906/ProposalAAHPM.pdf
42. Coalition to Transform Advanced Care. *Advanced Care Model (ACM) Service Delivery and Advanced Alternative Payment Model* (October 2017). Available at https://aspe.hhs.gov/system/files/pdf/253406/ACM.pdf

43. The PTAC comments and recommendations regarding the AAHPM and CTAC proposals were submitted to the Secretary of Health and Human Services on May 7, 2018 and are available at https://aspe.hhs.gov/system/files/pdf/255906/PTACCommentsRecommendationAAHPMCTAC.pdf

44. The evaluation of the Comprehensive Primary Care demonstration and the first-year evaluation of the CPC+ demonstration both found that the reductions in total Medicare spending for the patients receiving care from participating practices were not sufficient to offset the additional payments made to the participating primary care practices. Mathematica Policy Research, *Evaluation of the Comprehensive Primary Care Initiative: Fourth Annual Report* (May 2018). Available at https://downloads.cms.gov/files/cmmi/CPC-initiative-fourth-annual-report.pdf. Mathematica Policy Research. *Independent Evaluation of Comprehensive Primary Care Plus (CPC+): First Annual Report* (April 2019), available at https://downloads.cms.gov/files/cmmi/cpcplus-first-ann-rpt.pdf.

NOTE: Harold Miller is a member of the Physician-Focused Payment Model Technical Advisory Committee (PTAC), but the comments in this report are not intended to represent the position of the PTAC as a whole or of other individual members. PTAC's statutory charge is limited to reviewing proposals for payment models that are submitted to it by stakeholders, and it has no role in advising HHS or CMS other than submitting comments and recommendations on the proposals it receives.

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