

2015 ANNUAL REPORT

DEAR SUPPORTERS:

With your continued support, the Alliance for Patient Access and Institute for Patient Access have experienced unprecedented growth in 2015.

Now in its ninth year, AfPA enjoys the support of over 700 physicians and health care providers. IfPA has expanded its capacity to inform the public about pivotal health policy access issues. And as AfPA and IfPA continue to communicate how the physician-patient relationship drives quality health care, they target an increasing range of issues areas with innovative educational resources.

New Issue Areas & Working Groups

This year, AfPA stepped up to meet the growing need for advocacy in the areas of patient access to hepatitis and respiratory therapies by creating two new working groups. The *Hepatitis Therapy Access Physicians Working Group* convened its first two meetings, identified group leadership, and issued its first white paper and policy video. The *Respiratory Therapy Access Physicians Working Group* held its inaugural meeting in November to identify key challenges for its health care providers and their patients. Both groups look forward to continued growth in 2016.

The Global Alliance for Patient Access extended its scope to encompass advocacy efforts in Latin America, Europe, Australia, and Asia. While continuing to address patient access challenges related to biological therapies, GfPA also initiated advocacy efforts for oncology and pain management therapies.

AfPA assumed leadership of the *National Coalition for Infant Health*, formerly the National Premature Infant Health Coalition. Under AfPA, the coalition has benefitted from the leadership of a new medical director, initiated a series of educational policy briefs, and held an incredibly successful national policy summit.

New Online Resources

AfPA introduced two new online resources to support patient access education and advocacy. *Prescription Process* is a comprehensive online center for education, legislative tracking, and advocacy related to the challenges patients face in

accessing their prescription medications. *SurveyHub* provides a repository of attitudinal research on patient, physician, and public opinions regarding health care access. Both websites supplement and support AfPA's broad base of advocacy efforts.

New Advocacy & Education Offerings

Finally, AfPA and IfPA continue to explore innovative ways to educate and advocate. This year AfPA expanded its video education offerings to include white board, or "quick draw", videos. These complement AfPA's traditional videos by taking a brief, straightforward look at specific policy challenges such as step therapy, biosimilar substitution, medication labeling, and clinical pathways.

IfPA took a bold step in co-sponsoring the 2015 Preemie Matters National Policy Summit. The event brought together members of Congress, advocates, parents, health care providers, and industry representatives to explore the health care needs of preterm infants and their families. The event's success opened a new and valuable avenue for advocacy.

With this annual report, we mark the achievements of 2015 and express our sincere appreciation for stakeholders, health care providers, and advocacy partners who helped make 2015 a year of progress toward our continued goal: patient access to approved medical therapies and appropriate clinical care.

Sincerely,



Brian Kennedy
Executive Director



David Charles, MD
National Chairman

2015 BY THE NUMBERS



700+ AfPA members



9 policy briefs



42,825

2015 YouTube video views



603

Facebook friends



632

Twitter followers



states represented by AfPA members



37 competencies represented by AfPA members

1,401

e-newsletter recipients



18



events and meetings sponsored

41



physician legislators in AfPA's Health Policy Council

47



congressional champion awards presented

105



blog postings

5 working groups



3 continents on which AfPA/GAfPA produced programming

2015 ANNUAL REPORT

TABLE OF CONTENTS

4 BIOLOGICS

- 5 Distinct Medicines Need Distinct Names
- 6 Informed Prescribing Requires Transparent Labeling
- 8 Communication Protects Patients—
and the Physician-Patient Relationship

9 PAIN

- 10 Multi-faceted Pain Requires Multi-prong Treatment
- 11 Protecting Access While Curbing Abuse

13 ONCOLOGY

- 14 Burdensome Cost-sharing Undercuts Cancer Care
- 15 Breakthrough Therapies Present Access Challenges
- 15 Cost-focused Pathways Hinder Individualized Care
- 16 Do Value Models Reflect Patients' Values?

18 HEPATITIS

- 19 Care Rationing Blocks Patient Access
- 20 Lengthy Prior Authorizations Delay Vital Treatment

22 ADVOCACY INITIATIVES OF AFPA & IFPA

- 23 Clinical Trials Awareness
- 25 Infant Health
- 26 Respiratory Access



1 BIOLOGICS

DISTINCT MEDICINES NEED DISTINCT NAMES

INFORMED PRESCRIBING REQUIRES
TRANSPARENT LABELING

COMMUNICATION PROTECTS PATIENTS—
AND THE PHYSICIAN-PATIENT RELATIONSHIP

MESSAGE: DISTINCT MEDICINES NEED DISTINCT NAMES



VIDEO

A PRESCRIPTION
FOR SAFE
BIOLOGICS



“Distinct names help physicians and regulators track adverse responses. Physicians and patients must know with certainty which medication was taken—the original biologic or the biosimilar.”



INFOGRAPHIC

WHAT IS INDICATION
EXTRAPOLATION?



¿QUE ES LA EXTRAPOLACIÓN DE INDICACIONES?

Y ¿debe ser permitida con los
medicamentos biológicos?



MEDICAMENTOS GENÉRICOS

Copias químicas de
medicamentos
innovadores
de marca.

Porque son
idénticos, se supone
que actuarán de la
misma manera que
medicamentos de
marca en todas las
enfermedades y
condiciones.

BIOLOGICOS
GENÉRICOS
NO PUEDEN
EXISTIR

BIOLOGICOS

Son producidos por
organismos vivos o
células.

Se somete a
pruebas exhaustivas
para las condiciones
(indicaciones) que
están aprobadas para
tratar.

A diferencia de los
medicamentos
genéricos, no es
posible producir una
copia exacta de un
medicamento
biológico.



BIOSIMILARES

Medicamentos
biológicos diseñados
para ser similares a los
medicamentos
innovadores que ya
están aprobados.

Los legisladores
están considerando
actualmente en que
medida estos
medicamentos deben
ser probados en
pacientes con
diferentes
enfermedades.

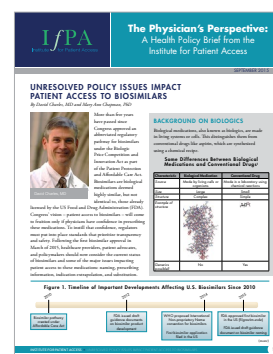


BRIEF

UNRESOLVED
POLICY ISSUES
IMPACT PATIENT
ACCESS TO
BIOSIMILARS



“Congress’ vision—patient access to biosimilars—will come to fruition only if physicians have confidence in prescribing these medications. To instill that confidence, regulators must put into place standards that prioritize transparency and safety.”



MESSAGE: INFORMED PRESCRIBING REQUIRES TRANSPARENT LABELING



INFOGRAPHIC



Rx *Transparent Biosimilar Labeling*



BASIC IDENTIFICATION

Prescribing information should indicate if the medication is a biosimilar.



STUDY SOURCE

Prescribing information should indicate whether each study was conducted with the biosimilar or original biologic.



TESTING DATA

Prescribing information should include data from studies with the biosimilar.



TESTING GROUPS & DISEASE STATES

Prescribing information should specify the patient groups and disease states in which the biosimilar was tested.

BRIEF

INFORMED
PRESCRIBING:
*Physicians Need
Complete and
Specific Prescribing
Information for
Biosimilar Medications*

IfPA
Institute for Patient Access

“Using the original biologic’s prescribing information for a biosimilar is an approach that lacks transparency. It fails to provide physicians with full information about the biosimilar, even though physicians are responsible for prescribing the medication and treating adverse side effects that may result.”



VIDEO

WHAT PHYSICIANS
NEED TO KNOW TO
SAFELY PRESCRIBE
BIOSIMILARS

AfPA
Alliance for Patient Access

“The approval of biosimilars is an important step toward improving patient access to medical therapies. With complete and transparent data about these medications, physicians can have the information they need to give patients the best care possible.”



BLOG

BILLING CODE
PROPOSAL RAISES
PATIENT SAFETY
CONCERNS

IfPA
Institute for Patient Access

“CMS’ recently proposed rule approaches biosimilar coding as it would with conventional medications and their generic counterparts. The strategy ignores subtle differences between biologics and biosimilars, as well as the challenges of potential immune responses from patients taking biological medications.”

MESSAGE: COMMUNICATION PROTECTS PATIENTS—AND THE PHYSICIAN-PATIENT RELATIONSHIP



GOV. BROWN GETS A SECOND CHANCE ON BIOSIMILAR MEDICINES

HUFFSTUTTER: KEEP PHYSICIAN-PATIENT RELATIONSHIP HEALTHY IN 2015



“...As more biosimilar medicines become available, most patients will want their doctor—not their pharmacist—deciding which medication is right for them. At the very least, they’ll want their doctor to know which medication they’re taking.”



Robin Dore, MD

“Ultimately, this legislation is about protecting the physician-patient relationship, because physicians need accurate information to monitor patients’ progress with disease progression and medication side effects to direct treatment.”



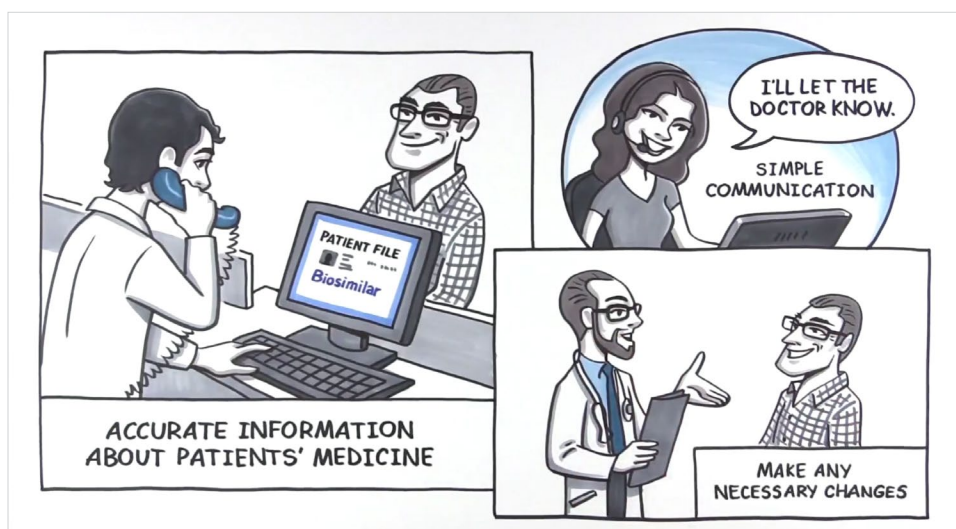
Dr. Joseph Huffstutter



HOW TO SAFELY, EFFECTIVELY SUBSTITUTE BIOLOGICAL MEDICINES



“With communication provisions in place, physicians can have confidence they know which biologic medicine their patient is taking.”





2 PAIN

MULTI-FACETED PAIN REQUIRES MULTI-PRONG TREATMENT
PROTECTING ACCESS WHILE CURBING ABUSE

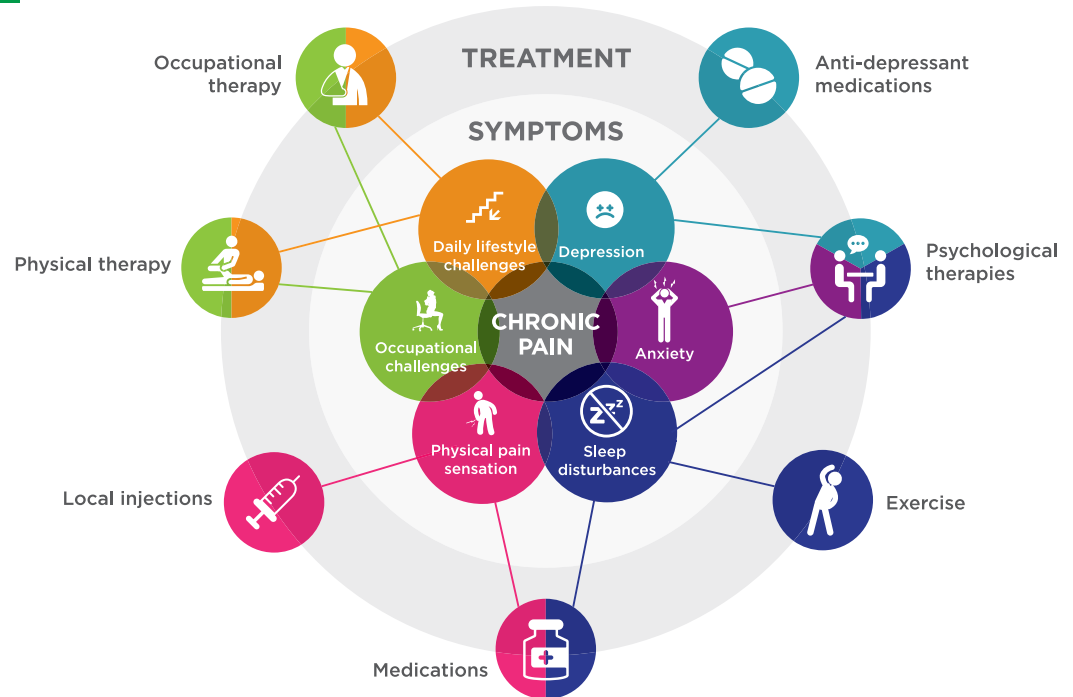
MESSAGE: MULTI-FACETED PAIN REQUIRES MULTI-PRONG TREATMENT

INFOGRAPHIC

AfPA
Alliance for Patient Access

Integrated Care Addresses the Multiple Features of Chronic Pain

Pain is multifaceted. So is its treatment.

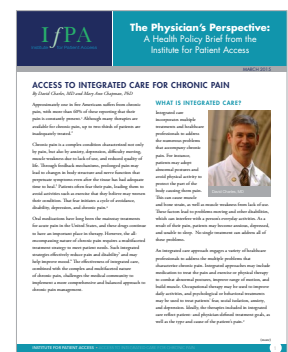


BRIEF

ACCESS TO
INTEGRATED CARE
FOR CHRONIC PAIN

I fPA
Institute for Patient Access

“The effectiveness of integrated care, combined with the complex and multifaceted nature of chronic pain, challenges the medical community to implement a more comprehensive and balanced approach to chronic pain management.”



MESSAGE: PROTECTING ACCESS WHILE CURBING ABUSE



VIDEO

A PRESCRIPTION
FOR REDUCING
OPIOID ABUSE



“For this new technology to help reduce prescription opioid abuse, it must be available to the patients who need it.”

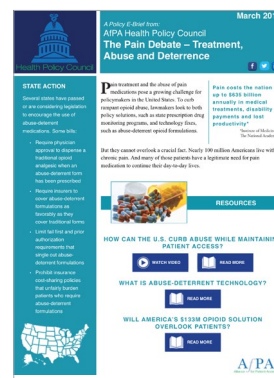


E-BRIEF

THE PAIN DEBATE



“Several states have passed or are considering legislation to encourage the use of abuse-deterrent medications.”



INFOGRAPHIC



**Without access
abuse-deterrent pain
medications can't
help the patients
who need them.**



**ABUSE-DETERRENT
FORMULATION**

BLOG

**“PILL MILL”
CRACKDOWNS
CREATE NEW PAIN
FOR PATIENTS**



“Crackdowns on so-called pill mills—pain management centers where financially motivated physicians over prescribe opioid pain medications—are designed to reduce abuse and overdoses. But in several states, these efforts are impeding access for patients with a legitimate medical need for pain management.”



3 ONCOLOGY

BURDENSOME COST-SHARING UNDERCUTS CANCER CARE

BREAKTHROUGH THERAPIES PRESENT ACCESS CHALLENGES

COST-FOCUSED PATHWAYS HINDER INDIVIDUALIZED CARE

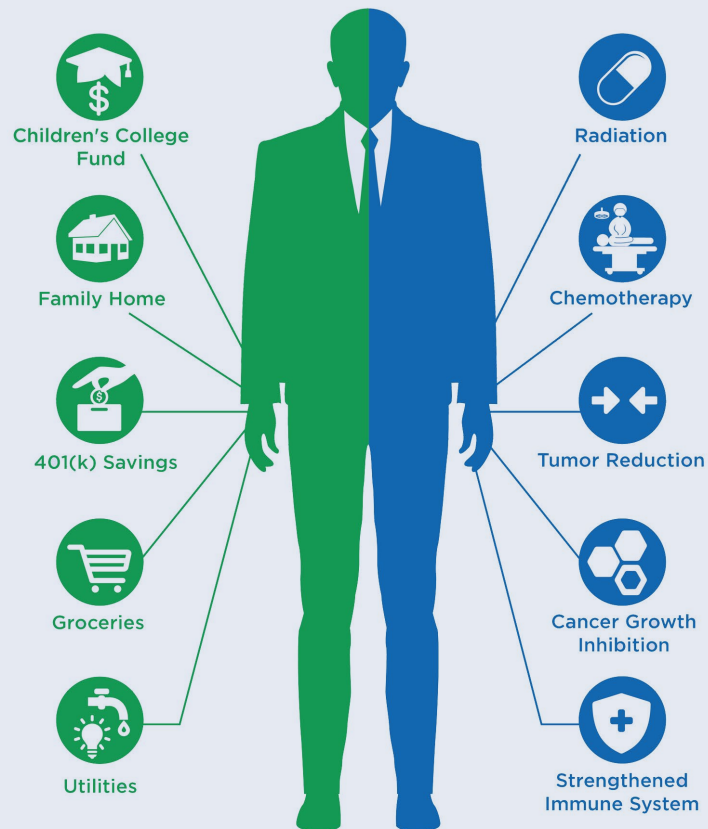
DO VALUE MODELS REFLECT PATIENTS' VALUES?

MESSAGE: BURDENSOME COST-SHARING UNDERCUTS CANCER CARE

INFOGRAPHIC

AfPA
Alliance for Patient Access

YOUR MONEY OR YOUR LIFE?



ONLINE RESOURCE

SPECIALTY TIERS

PRESCRIPTION
PROCESS

“Specialty tier medications may include treatments for cancer, multiple sclerosis, psoriasis, kidney disease and other life-threatening or debilitating diseases. These medications, like oral medicines for cancer, may cost a patient between 25 to 50 percent of the total cost of the drug...patients could...pay thousands of dollars each year for their medication.”

MESSAGE: BREAKTHROUGH THERAPIES PRESENT ACCESS CHALLENGES



BRIEF

IMPROVING
PATIENT ACCESS
TO IMMUNO-
ONCOLOGY
THERAPIES



“Clinical studies showing that immuno-oncology can help some patients with advanced cancer who don’t respond to other treatments have excited researchers, patients, and healthcare providers alike.”



Alan Marks, MD

MESSAGE: COST-FOCUSED PATHWAYS HINDER INDIVIDUALIZED CARE



VIDEO

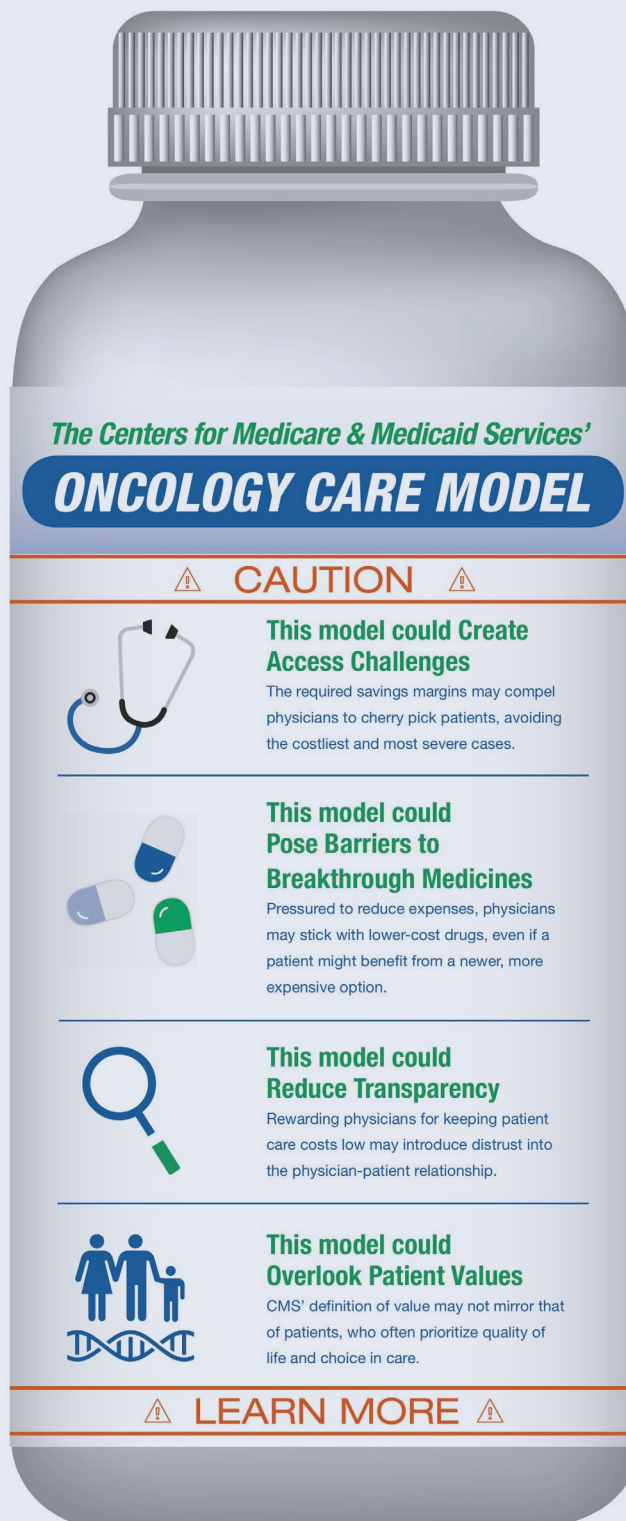
CLINICAL
PATHWAYS:
*When Personalized
Health Care Goes
Off Course*



“When clinical pathways prioritize cost-savings instead of individual patients, they can have an unpleasant result: a one-size-fits-all approach to patient care.”



MESSAGE: DO VALUE MODELS REFLECT PATIENTS' VALUES?



BLOG

ASCO VALUE
FRAMEWORK
SPARKS DIALOGUE
ON PATIENT-
CENTERED CARE

NCCN VALUE
TOOL OVERLOOKS
KEY ACCESS
FACTORS



“ASCO’s value framework... acknowledges the importance of the physician-patient relationship, though some stakeholders question whether it adequately reflects patients’ experiences and needs.”

“The [National Comprehensive Cancer Network] blocks score blood cancer therapies on a scale of one to five... But the approach overlooks a key factor—whether out-of-pocket costs allows for patients to access these medications in the first place.”

EARNED MEDIA

GOING FOR
BROKE: CMS’
ONCOLOGY CARE
MODEL COMES
WITH A PRICE



“We might consider not just what such a model will save—but what it might cost in the form of a redefined approach to cancer care.”



Alan Marks, MD





4 HEPATITIS

CARE RATIONING BLOCKS PATIENT ACCESS

LENGTHY PRIOR AUTHORIZATIONS DELAY VITAL TREATMENT

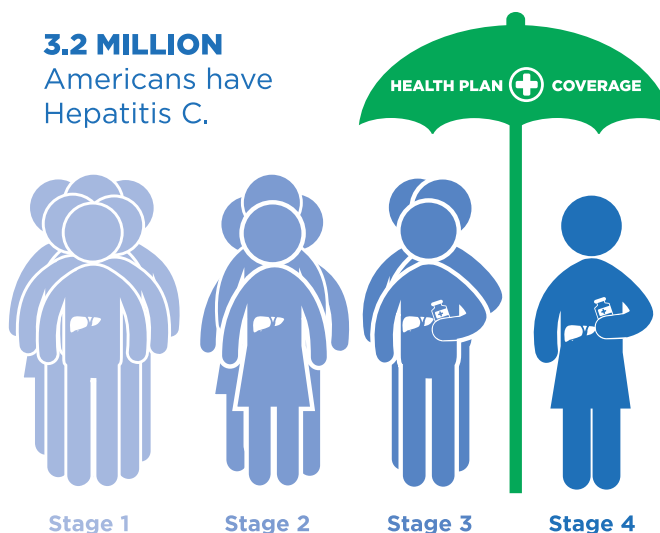
MESSAGE: CARE RATIONING BLOCKS PATIENT ACCESS

INFOGRAPHIC



WHICH PATIENTS ARE SICK ENOUGH FOR A HEPATITIS C CURE?

3.2 MILLION
Americans have
Hepatitis C.



Under many health plans,
only the sickest can receive
the cure they need.

SURVEY

1 IN 4 PATIENTS
INITIALLY DENIED
TREATMENT



KEY FINDINGS

Of patients prescribed sofosbuvir/ledipasvir to cure them of hepatitis C:

- **77%** received initial approval; About **23%** received initial rejection
- Nearly **14%** of those initially rejected did receive treatment through the appeals process
- Patients had to wait an average of **26** days for a final approval or rejection decision on coverage

Yale University School of Medicine, August 2015



Health Policy Council

 BLOG

IfPA
Institute for Patient Access

“Curing hepatitis C before senior citizens age into Medicare could save tens of thousands of lives. And as a new study from Milliman reports, it could also save the Medicare system \$3.9 billion over 10 years.”

MESSAGE: LENGTHY PRIOR AUTHORIZATIONS DELAY VITAL TREATMENT



BLOG

CMS NOTICE
URGES ACCESS TO
HEPATITIS C CURES
FOR MEDICAID
PATIENTS



“The Centers for Medicare and Medicaid Services has [a message](#) for state Medicaid programs: coverage policies cannot block hepatitis C patients’ access to ‘effective, clinically appropriate and medically necessary treatments.’”

WHITE PAPER

IMPROVING
PATIENT ACCESS
TO HEPATITIS C
CURES



“My patients don’t want to wait until they have advanced liver disease to be cured of hepatitis C, and many have not responded or failed treatment due to side effects of the older treatments.”



Robert G. Gish, MD



**Hepatitis Therapy
Access** Physicians
Working Group

VIDEO

IMPROVING
PATIENT ACCESS
TO HEPATITIS C
CURES



“Some patients will need to qualify through an extensive prior authorization process to get their medication. Such processes can include over a dozen individual requirements.”





5 ADVOCACY INITIATIVES OF AFPA & IFPA

CLINICAL TRIALS AWARENESS

INFANT HEALTH

RESPIRATORY ACCESS

BARRIERS TO PATIENT ACCESS

CLINICAL TRIALS AWARENESS



CLINICAL TRIALS
AWARENESS WEEK



STALLED
CLINICAL TRIALS:
*The Enrollment
Problem*



“Breakthrough medicines have the potential to treat cancer, Alzheimer’s, heart disease and many other conditions. But without participants joining clinical trials, these treatments never become available to patients.”



★ EVENT

2015 CLINICAL TRIALS AWARENESS NATIONAL CONFERENCE



📄 WHITE PAPER

"SHARE YOUR LIFE. SHARE YOUR DECISION."
How the Campaign to Increase Organ Donations Provides a Model for Public Health Awareness Efforts



"Given the similarities between organ donation and clinical trials, a campaign similar to the organ donation initiative would likely be effective in promoting clinical trials awareness and participation."



📊 INFOGRAPHIC



INFANT HEALTH



EVENT

PREEMIE MATTERS
NATIONAL POLICY
SUMMIT

NCfIH
National Coalition
for Infant Health

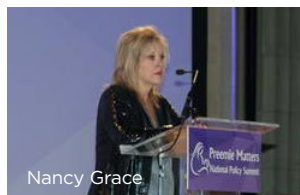


Preemie Matters National Policy Summit

“The Preemie Matters summit provided a solid foundation for a national strategy to guide the coalition in educating policymakers, the public, and media on issues regarding access and appropriate clinical standards. It was a success thanks to our expert panelists, informed speakers and engaged attendees.”



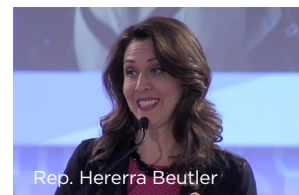
Mitchell Goldstein, M.D.,
Medical Director,
National Coalition
for Infant Health



Nancy Grace



Rep. Katherine Clark



Rep. Herrera Beutler



RESPIRATORY ACCESS

BLOG

PATIENTS WITH
RESPIRATORY
CONDITIONS
STRUGGLE TO
ACCESS NEEDED
MEDICATIONS



“For many Americans with respiratory conditions, the struggle to breathe is now exacerbated by the struggle to pay out-of-pocket expenses for the medications that alleviate their symptoms.”

BLOG

WILL
RECOMMENDATION
AGAINST COPD
SCREENING
UNDERMINE EARLY
DIAGNOSIS?



“...The recommendation would virtually eliminate the short, self-administered questionnaires now used in clinical settings throughout the country. Such questionnaires currently aid physicians in identifying patients who need follow-up and further testing, which can help especially with patients unfamiliar with COPD symptoms.”

SURVEY

SEVERE ASTHMA
DISRUPTS PATIENTS'
EVERYDAY LIVES



KEY FINDINGS

- **32%** patients reported that their severe asthma negatively affected their social life
- **23%** patients reported it affected their work life
- **18%** patients reported it affected their family life

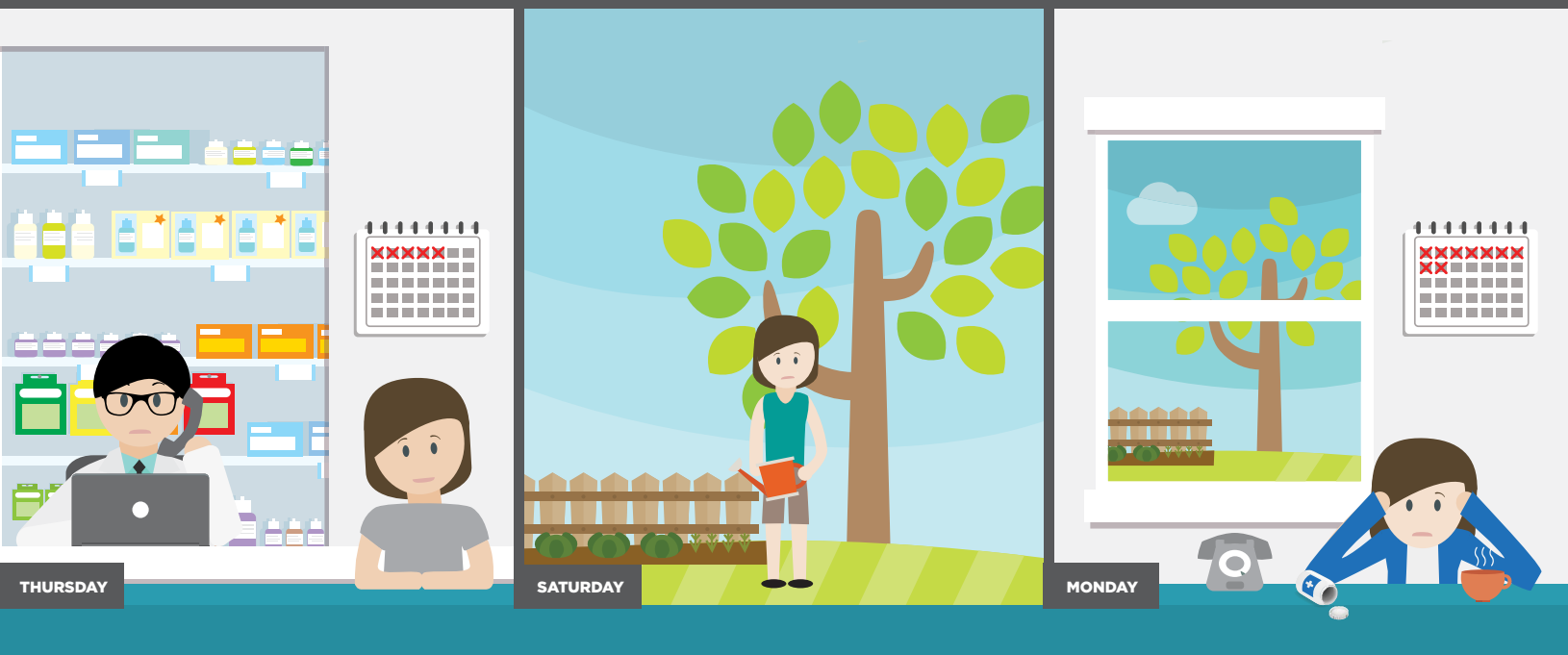
BARRIERS TO PATIENT ACCESS

INFOGRAPHIC

AfPA
Alliance for Patient Access



Lengthy prior authorization processes
delay patient access to vital medications.



ONLINE RESOURCE

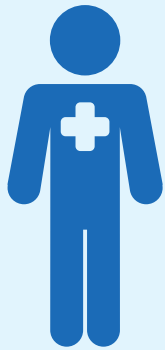
NON-MEDICAL
SWITCHING

PRESCRIPTION
PROCESS

“Non-medical switching does not just ignore the process physicians and patients underwent to find a successful medical therapy. It also disregards the impact of switching medications arbitrarily.”

WHEN CANCER COST-SHARING TURNS TOXIC.

Are insurers' cost-shifting policies pricing cancer patients out of care?



\$4,800

The average amount that an insured cancer patient pays out of pocket per year is \$4,800



50% \$\$\$\$\$\$\$\$\$\$

of Medicare beneficiaries with cancer spend **more than 10%** of their income on out-of-pocket health care costs.



28% \$\$\$\$\$\$\$\$\$\$

spend **more than 20%**.



Between 1999 and 2013, patients' share of premiums has **increased by 196%**. Deductibles have almost doubled.



2.65x

Cancer patients were **2.65 times more** likely to go bankrupt than people without cancer.



70%

Patients with higher co-payments (**\$53 or more**) were **70% more** likely to discontinue therapy in the first six months of treatment.

When cost-sharing turns toxic, patients may fall into nonadherence—spacing out chemotherapy appointments, delaying care, declining diagnostic procedures, and replacing prescription therapies with over-the-counter medications.

Pharmacy Practice News, January 2015

BLOG

EXCHANGE PLANS' COST-SHARING CONFUSES, BURDENS PATIENTS

I f P A
Institute for Patient Access

“Lacking cost-sharing details can be worse than inconvenient. For patients who depend upon medication to sustain quality of life—or life itself—surprise out-of-pocket costs could put vital medications out of reach.”

VIDEO

UNDERSTANDING
STEP THERAPY



“Despite their years of medical training, doctors’ judgment—and the doctor-patient relationship—are being undermined by step therapy.”

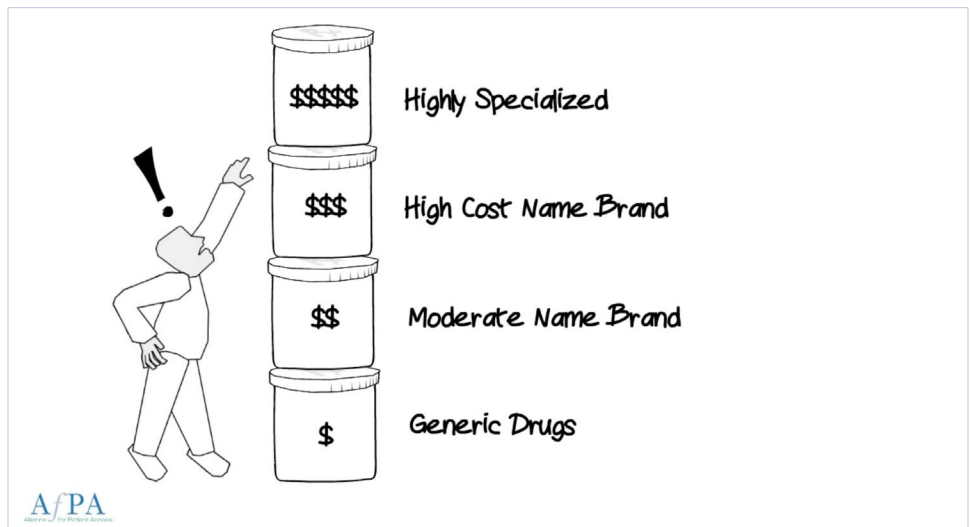


VIDEO

THE COST OF
SPECIALTY TIERS



“Sometimes the patients who need the drugs the most can’t access them because of cost.”



AfPA
Alliance for Patient Access

IfPA
Institute for Patient Access

ALLIANCEFORPATIENTACCESS.ORG