AACVPR
American Association of Cardiovascular and Pulmonary Rehabilitation
Promoting Health & Preventing Disease

How the Cardiopulmonary Rehabilitation Act Became Law: Background, Benefits & Regulations

Larry F. Hamm, PhD, FAACVPR
George Washington University Medical Center
Washington, DC, USA

Angioplasty Summit-TCTAP 2010
Seoul, Korea

AACVPR
American Association of Cardiovascular and Pulmonary Rehabilitation
Promoting Health & Preventing Disease

GWU Medical Center

Korean Embassy

KACVPR Affiliation

2009 Cardiac Rehab Workshop

AACVPR
American Association of Cardiovascular and Pulmonary Rehabilitation
Promoting Health & Preventing Disease

1. BACKGROUND

Health Care in The U.S.

- Providers
  - Private provider systems
  - Government provider systems
- Health insurance
  - Private insurance companies
    - Blue Cross, Aetna, Group Health
  - Government insurance plans
    - Medicare, Medicaid

AACVPR
American Association of Cardiovascular and Pulmonary Rehabilitation
Promoting Health & Preventing Disease

Health Insurance Coverage

- Some services are "covered benefits" while others are "not covered"
- Era of **evidence-based practice**
  - To large extent, coverage is determined by the clinical evidence
- If service is covered, level of payment may be **performance-based**

AACVPR
American Association of Cardiovascular and Pulmonary Rehabilitation
Promoting Health & Preventing Disease

Cardiac (CR) & Pulmonary Rehabilitation (PR) Evidence

- The level of evidence in the clinical literature for CR is very good (1-B)
- CR/exercise training is included in 10 current guidelines and scientific statements from the AHA and ACC
- PR evidence is also good and is recognized & defined by several clinical guidelines

AACVPR
American Association of Cardiovascular and Pulmonary Rehabilitation
Promoting Health & Preventing Disease

Classifying Recommendations & Level of Evidence

"Size of Treatment Effect"

	Class I *Benefit >>> Risk* Procedure/Treatment SHOULD be performed/administered	Class IIa *Benefit >> Risk* *Additional studies with focused objectives needed* IT IS REASONABLE to perform procedure/administer treatment	Class IIb *Benefit ≥ Risk* *Additional studies with broad objectives needed; Additional registry data would be helpful* Procedure/Treatment MAY BE CONSIDERED	Class III *Risk ≥ Benefit* *No additional studies needed* Procedure/Treatment should NOT be performed/administered SINCE IT IS NOT HELPFUL AND MAY BE HARMFUL
Level A *Multiple (3-5) population risk strata evaluated** *General consistency of direction and magnitude of effect*	• Recommendation that procedure or treatment is useful/effective • Sufficient evidence from multiple randomized trials or meta-analyses	• Recommendation in favor of treatment or procedure being useful/effective • Some conflicting evidence from multiple randomized trials or meta-analyses	• Recommendation's usefulness/efficacy less well established • Greater conflicting evidence from multiple randomized trials or meta-analyses	• Recommendation that procedure or treatment not useful/effective and may be harmful • Sufficient evidence from multiple randomized trials or meta-analyses
Level B *Limited (2–3) population risk strata evaluated**	• Recommendation that procedure or treatment is useful/effective • Limited evidence from single randomized trial or non-randomized studies	• Recommendation in favor of treatment or procedure being useful/ effective • Some conflicting evidence from single randomized trial or non-randomized studies	• Recommendation's usefulness/efficacy less well established • Greater conflicting evidence from single randomized trial or non-randomized studies	• Recommendation that procedure or treatment not useful/effective and may be harmful • Limited evidence from single randomized trial or non-randomized studies
Level C *Very limited (1–2) population risk strata evaluated**	• Recommendation that procedure or treatment is useful/effective • Only expert opinion, case studies, or standard-of-care	• Recommendation in favor of treatment or procedure being useful/ effective • Only diverging expert opinion, case studies, or standard-of-care	• Recommendation's usefulness/efficacy less well established • Only diverging expert opinion, case studies, or standard-of-care	• Recommendation that procedure or treatment not useful/effective and may be harmful • Only expert opinion, case studies, or standard-of-care

TABLE 3. Applying Classification of Recommendations and Level of Ev

AACVPR
American Association of Cardiovascular and Pulmonary Rehabilitation
Promoting Health & Preventing Disease

- **Use of CR included in many ACC/AHA practice guidelines**
  - Preventing heart attack & death in patients with coronary & other atherosclerotic vascular disease
  - STEMI
  - Unstable angina/non-STEMI
  - Chronic stable angina
  - PCI
  - CABG
  - Heart failure
  - Valvular heart disease
  - PAD
  - CVD prevention in women

AACVPR
American Association of Cardiovascular and Pulmonary Rehabilitation
Promoting Health & Preventing Disease

PR Guidelines

- Nici L, Donner C, Wouters E, et al. American Thoracic Society/European Respiratory Society Statement on pulmonary rehabilitation. Am J Respir Crit Care Med 2006; 173:1390-1413
- Reis AL, Bauldoff GS, Carlin BW, et al. Pulmonary rehabilitation: joint ACCP/AACVPR evidence-based clinical practice guidelines. Chest 2007;131:4-42
- Global Initiative for Chronic Obstructive Lung Disease (GOLD). Update 2007. http://www.goldcopd.org

AACVPR
American Association of Cardiovascular and Pulmonary Rehabilitation
Promoting Health & Preventing Disease

Health Care Services Coverage

- Regulatory
  - Centers for Medicare and Medicaid Services (CMS)
  - Insurance Medical Directors
- Legislative (Statutory)
  - Services mandated by law through the passage of federal legislation

AACVPR
American Association of Cardiovascular and Pulmonary Rehabilitation
Promoting Health & Preventing Disease

CR Coverage History

- Services have been covered by regulations since inception without being mandated by law
- CMS has had 2 National Coverage Determinations (NCDs) for CR
- New federal law took effect in January 2010

AACVPR
American Association of Cardiovascular and Pulmonary Rehabilitation
Promoting Health & Preventing Disease

PR Coverage History

- No past NCD
- Coverage and payment for services has been geographically variable
- New federal law took effect January 2010

AACVPR
American Association of Cardiovascular and Pulmonary Rehabilitation
Promoting Health & Preventing Disease

Why Did We Need Legislation?

AACVPR
American Association of Cardiovascular and Pulmonary Rehabilitation
Promoting Health & Preventing Disease

3 Major Issues

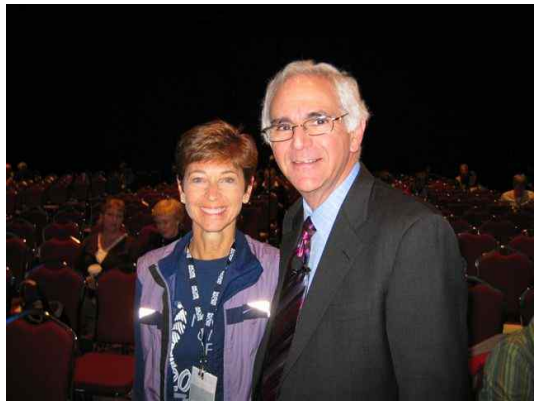
1. **Cardiac rehabilitation** was "incident to" physician service and that created regulatory **uncertainty** and **confusion** concerning the required level of physician supervision and compliance with Medicare regulations
2. **No** NCD for **pulmonary rehabilitation**
3. **Neither** were a mandated benefit

AACVPR
American Association of Cardiovascular and Pulmonary Rehabilitation
Promoting Health & Preventing Disease

What Was the Process?

1. BOD Commitment

+



2. Legislative Analysts

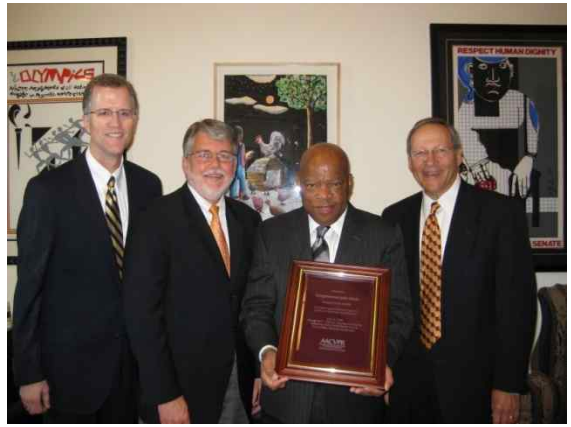
+

3. Grassroots Activity

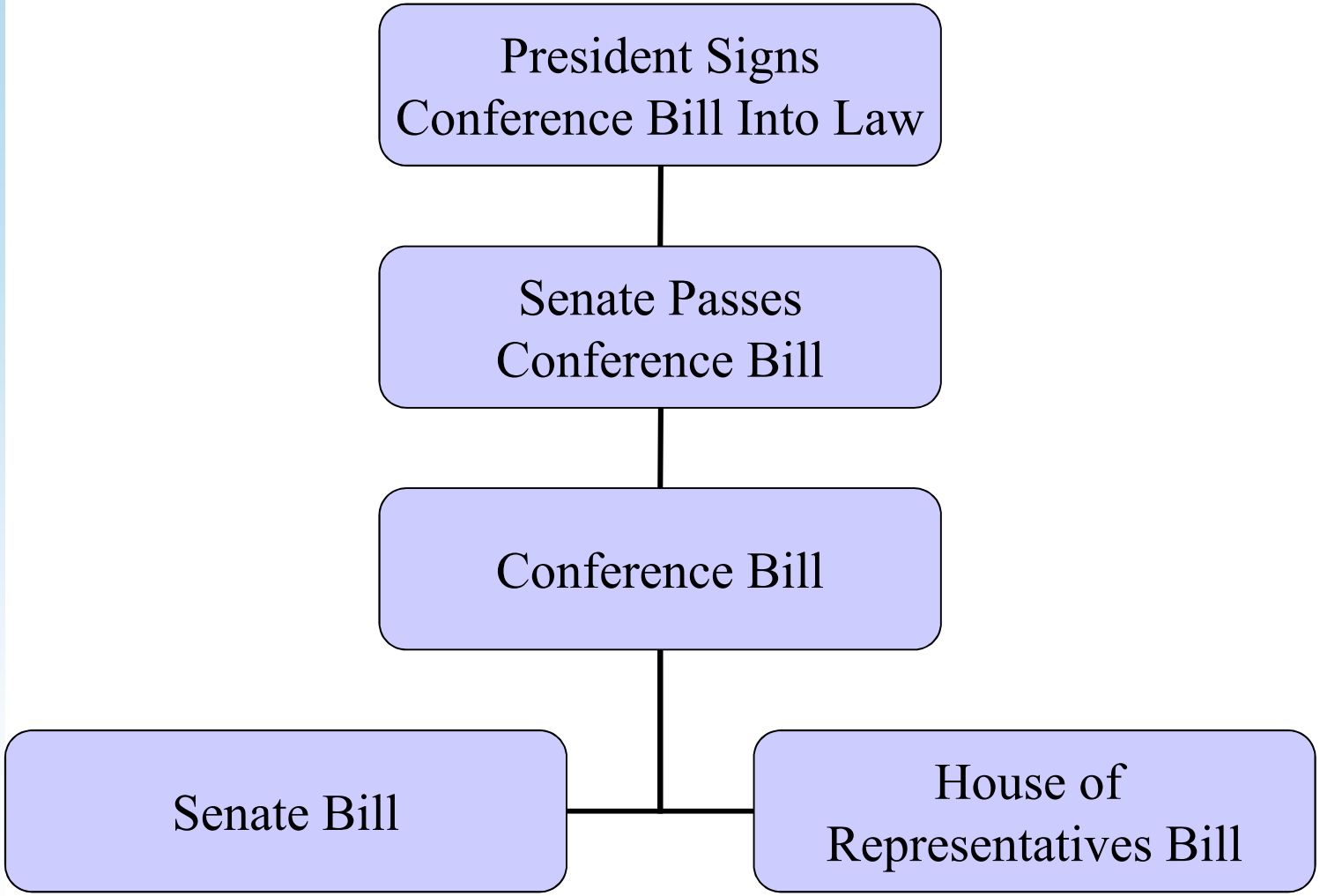
+

4. Member Involvement

+



5. Thank-you


President Signs Conference Bill Into Law
Senate Passes Conference Bill
Conference Bill
Senate Bill
House of Representatives Bill

AACVPR
American Association of Cardiovascular and Pulmonary Rehabilitation
Promoting Health & Preventing Disease

The Medicare Improvement for Patients & Providers Act of 2008

122 STAT. 2544 PUBLIC LAW 110–275—JULY 15, 2008

SEC. 144. PAYMENT AND COVERAGE IMPROVEMENTS FOR PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE AND OTHER CONDITIONS.

(a) COVERAGE OF PULMONARY AND CARDIAC REHABILITATION.—

Effective January 1, 2010

AACVPR
American Association of Cardiovascular and Pulmonary Rehabilitation
Promoting Health & Preventing Disease

2. BENEFITS

CR & PR Enshrined in Law

- Federal law now **mandates** CR & PR for all Medicare beneficiaries – 41,700,000 people

- Became effective January 1, 2010

AACVPR
American Association of Cardiovascular and Pulmonary Rehabilitation
Promoting Health & Preventing Disease

3. REGULATIONS

AACVPR
American Association of Cardiovascular and Pulmonary Rehabilitation
Promoting Health & Preventing Disease

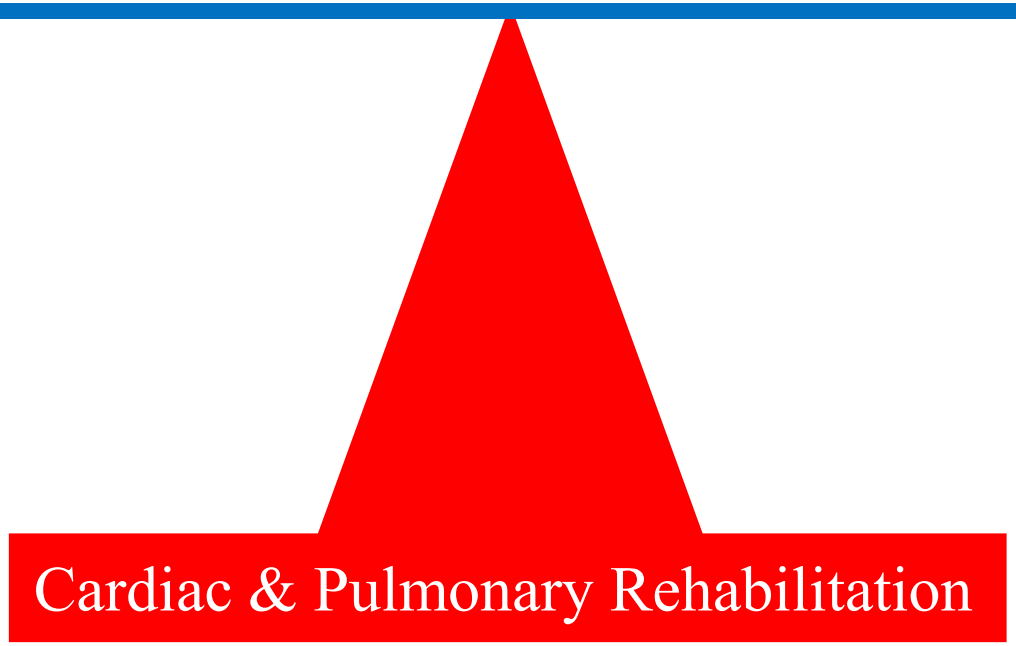
Balancing Regulatory & Legislative Issues

Regulatory

Centers for Medicare & Medicaid Services

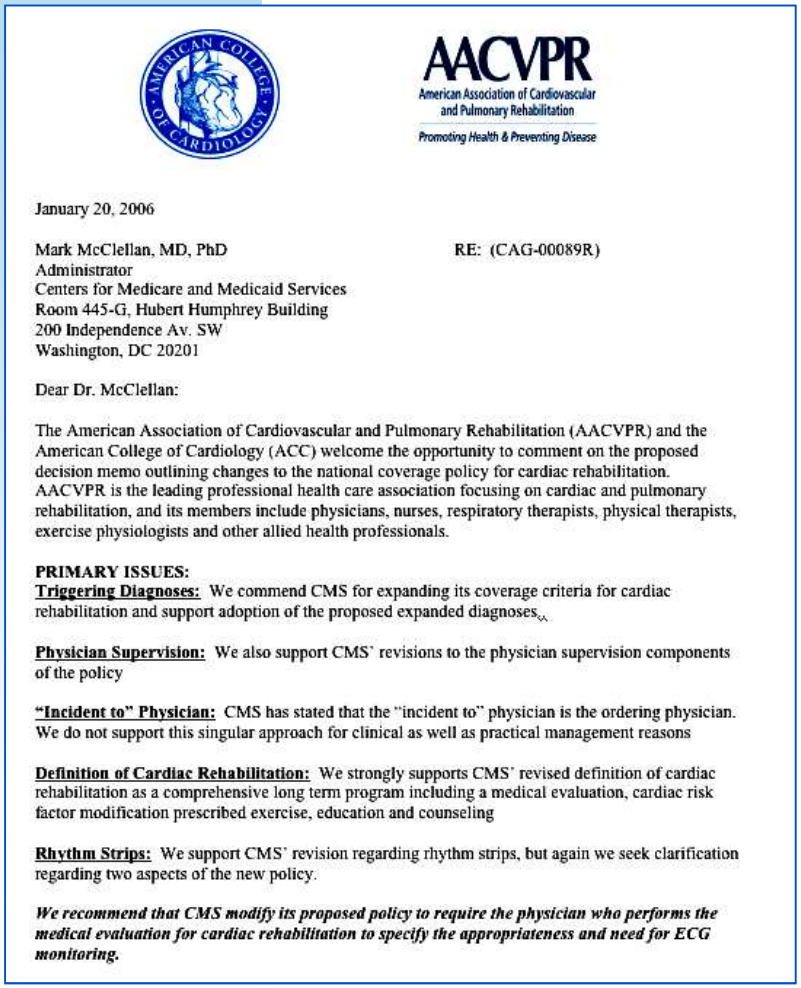
Legislative

Congress & Federal Law



AACVPR
American Association of Cardiovascular and Pulmonary Rehabilitation
Promoting Health & Preventing Disease

Important Regulatory Decision (2006)



AACVPR
American Association of Cardiovascular and Pulmonary Rehabilitation
Promoting Health & Preventing Disease

January 20, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Room 445-G, Hubert Humphrey Building
200 Independence Av. SW
Washington, DC 20201

RE: (CAG-00089R)

Dear Dr. McClellan:

The American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) and the American College of Cardiology (ACC) welcome the opportunity to comment on the proposed decision memo outlining changes to the national coverage policy for cardiac rehabilitation. AACVPR is the leading professional health care association focusing on cardiac and pulmonary rehabilitation, and its members include physicians, nurses, respiratory therapists, physical therapists, exercise physiologists and other allied health professionals.

PRIMARY ISSUES:

Triggering Diagnoses: We commend CMS for expanding its coverage criteria for cardiac rehabilitation and support adoption of the proposed expanded diagnoses.

Physician Supervision: We also support CMS' revisions to the physician supervision components of the policy

"Incident to" Physician: CMS has stated that the "incident to" physician is the ordering physician. We do not support this singular approach for clinical as well as practical management reasons

Definition of Cardiac Rehabilitation: We strongly supports CMS' revised definition of cardiac rehabilitation as a comprehensive long term program including a medical evaluation, cardiac risk factor modification prescribed exercise, education and counseling

Rhythm Strips: We support CMS' revision regarding rhythm strips, but again we seek clarification regarding two aspects of the new policy.

We recommend that CMS modify its proposed policy to require the physician who performs the medical evaluation for cardiac rehabilitation to specify the appropriateness and need for ECG monitoring.

CMS Centers for Medicare & Medicaid Services

The Centers for Medicare and Medicaid Services (CMS) determines:

The evidence is adequate to conclude that cardiac rehabilitation is reasonable and necessary following acute myocardial infarction (AMI), coronary artery bypass graft (CABG), stable angina pectoris, ***heart valve repair or replacement, percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting, and heart or heart lung transplant.***

AACVPR
American Association of Cardiovascular and Pulmonary Rehabilitation
Promoting Health & Preventing Disease

December 2009 CMS Regulations

- Developed because of new law
- Defined
  - Duration & frequency of sessions; length of program
    - 36 one-hour sessions allowed over 36 weeks
  - Number of sessions per day
    - Multiple sessions per day

AACVPR
American Association of Cardiovascular and Pulmonary Rehabilitation
Promoting Health & Preventing Disease

2009 CMS Regulations - 2

- Coverage
  - More flexible billing codes
  - CR: same 6 eligible diagnoses
  - PR: moderate – very severe COPD
- Required elements of services
- Individual treatment plan

AACVPR
American Association of Cardiovascular and Pulmonary Rehabilitation
Promoting Health & Preventing Disease

Ongoing & Future Regulatory Issues

- Expand covered diagnoses for both CR & PR
- Use of physician extenders for supervision
- Increase payments for services

AACVPR
American Association of Cardiovascular and Pulmonary Rehabilitation
Promoting Health & Preventing Disease

Summary of Important Elements for Success

- Commitment from leadership
- Legislative expertise
- Dedication of the membership
- Endurance, endurance, endurance

AACVPR
American Association of Cardiovascular and Pulmonary Rehabilitation
Promoting Health & Preventing Disease

Gamsa hamnida

Thank you