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The Implications of Comparative Effectiveness Research for Medicare

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Policy makers are looking to CER to increase value of health spending, help sustain Medicare

- Affordable Care Act of 2010 (ACA)
  - Created the Patient-Centered Outcomes Research Institute (PCORI) and set up trust fund to finance CER. $500 million+ per year for CER by 2014.
- American Recovery and Reinvestment Act of 2009 (ARRA)
  - Authorized $1.1 billion investment in CER and sets up federal coordinating committee.
- Medicare Modernization Act of 2003 (MMA)
  - Authorized AHRQ to fund CER on pharmaceuticals, devices, and health care services, partly to support sound decision-making under new Medicare drug benefit. $30 million appropriated.

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Development of evidence on CE is a long-standing and recurring interest of policy makers

- AHCPR created in 1989
  - $97 million initial appropriation. Charged with supporting outcomes research, health technology assessment and practice guidelines geared towards reducing health costs and ensuring Medicare sustainability
  - Appropriation reduced and controversial CER program dropped in 1995 following political debate that threatened agency's existence

- National Center for Health Care Technology (1978–1981)
  - Advised the Health Care Financing Administration (now CMS) on coverage decisions by examining new and existing technologies

So what's new and different now?

- Level of ARRA and ACA investment dwarfs previous public investments in CER
- New funding mechanism insulates new research institute (PCORI) from appropriations process
  - More stable and predictable, less subject to political interference
- Involvement of stakeholders in priority setting and development of research agenda
  - May reduce likelihood that PCORI and its research will be successfully challenged by those who stand to lose

So what's new and different now? (cont'd)

- Effort to coordinate and leverage current government and non-gov't investment, as well as existing research
- Renewed focus on framing questions in terms of what patients, physicians, payers need to know about relative effectiveness of alternatives for particular patients under particular circumstances
- Development of new data and use of research methods that allow researchers to answer questions accurately and timely

Use of CE information in Medicare represents a persistent challenge

- Should Medicare seek to influence providers' and beneficiaries' decisions on the basis of information about relative effectiveness?
- If so, which ways are appropriate and acceptable?
- Legislative history shows congressional ambivalence about use of Medicare policy to limit or constrain patient and provider choice
  - e.g., MMA prohibition on use of CER by Secretary of HHS to limit coverage for prescription drugs
- ACA provides some new authority for CMS, in terms of administrative flexibility and opportunities to innovate

Medicare policies make use of CE information: Coverage decisions

- National coverage decisions
  - In making Medicare's national coverage decisions, CMS assesses whether a given service is reasonable and necessary by determining:
    (1) if it is safe and effective per the FDA regulatory process; and
    (2) if the service improves net health outcome.
  - Information from CER can be used in CMS assessments, together with other information

- Defined limitations on coverage
  - CMS may limit coverage to patients under certain circumstances or to certain service providers, when judged to be warranted by evidence from CER

Medicare policies make use of CE information: Payment decisions

- Pass-through payments under PPS
  - Medicare's hospital inpatient and outpatient prospective payment systems consider CE in setting payment rates.
  - For a new technology to be eligible to receive a pass-through payment , it must represent an advance in medical technology that substantially improves diagnosis or treatment, relative to services previously available.

- Payment limits for services deemed equivalent
  - In some instances, Medicare payments for a service may be limited to the rate paid for the "least costly alternative"
    - MMA prohibited CMS from deeming services functionally equivalent (and subject to identical payment rate) for drugs and biologics provided in the hospital outpatient setting

Medicare policies support development of new information on CE

- Coverage with evidence development
  - In cases where evidence of effectiveness is needed, national coverage of a service may be limited to providers who participate in and beneficiaries who enroll in a prospective data collection activity.

- Clinical trials and data registries
  - Since 2000, Medicare pays the routine costs of care for patients who enroll in clinical trials that meet certain criteria.

How might the latest CER initiatives affect Medicare policy?

1. **Increase and strengthen the evidence base for Medicare coverage decisions**

- ACA authorizes use of CER in Medicare coverage decision-making, provided that:
  - Use is through an iterative and transparent process that includes public comment and considers effects on subpopulations

- ACA prohibits the use of CER information in Medicare decision-making in ways that:
  - Place higher value on extension of life for younger, nondisabled
  - interfere with personal judgments about trade-offs between extending life and increasing risk of disability

How might the latest CER initiatives affect Medicare policy? (cont'd)

2. Facilitate efforts to move toward value-based purchasing

- ACA providers for more flexibility and innovation in payment and delivery of care for beneficiaries in traditional Medicare
  - New CMS Center for Medicare and Medicaid Innovation charged with piloting new approaches

- Potential to modify provider payment levels so as to incentivize provision of relatively effective services, discourage less effective options
  - Differentiation of co-payments might be possible under some circumstances

- Potential to enter into risk-sharing agreements with innovation sponsors when evidence of CE is unclear

How might the latest CER initiatives affect Medicare policy? (cont'd)

3. Provide evidence for use in patient and provider decision-support tools

- AHRQ charged with assisting in the translation of CER findings for use with automated clinical decision support tools
- CMS charged with overseeing Medicare and Medicaid pilots on use of patient decision support tools

Will Medicare policies incorporate consideration of relative cost-effectiveness?

- HCFA's proposal to consider cost-effectiveness in national coverage decisions proposed in 1989, withdrawn in 1999 in face of substantial opposition
- ACA prohibits the Secretary from establishing cost-effectiveness thresholds to determine coverage, reimbursement or incentive programs
- Given outstanding public concern about prospects of using CE to ration services, explicit considerations of cost effectiveness appear unlikely in the short term

Medicare costs considerations could be taken into account otherwise

- Will PCORI research agenda development and prioritization take costs into account?

Any lessons from abroad? What's different in CER development and use…

- Most countries' CER programs exist to serve payers' needs for both information and advice
  - e.g., Canada's CADTH, England's NICE, Germany's IQWIG, Australia's PBAC , Sweden's TLV
  - PCORI is constrained from advising on policy; the research products it generates also

- Other countries' CER programs focus on research synthesis and secondary CER
  - Primary, original research to be important in PCORI agenda

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Lessons from abroad: Not so different, in other respects

- U.S. Medicare not alone in refraining from use of cost-effectiveness analysis in social insurance program coverage decision-making
  - e.g., France, Germany, Switzerland

- Decisions not to cover a particular service, drug or device always controversial, subject to scrutiny and pressure to reverse

Looking ahead: Medicare opportunities

- 25% of Medicare beneficiaries are enrolled in a private Medicare Advantage plan; 38% are in a private Prescription Drug Plan
  - Will private health plans be more or less able than traditional Medicare to bring CER evidence to bear in provider and patient decisions?

- To what extent will Accountable Care Organizations have the means and incentives to modify provider practice patterns in response to CE findings?

Looking ahead: Potential pitfalls

- Risk that any decision by Medicare payers or policy makers to restrict or limit treatment options will be viewed publicly as a judgment that benefits are too costly

Conclusions

- New CER investment is expected to provide more and better evidence about what works under what circumstances
- Creates opportunities to increase value of Medicare spending via improved outcomes, reduced use of inappropriate or unnecessary services
- Policy makers most comfortable with efforts to support and incent use of information by providers and patients in decision-making
- Policies that constrain and limit choices are more difficult and likely require a higher threshold of evidence

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