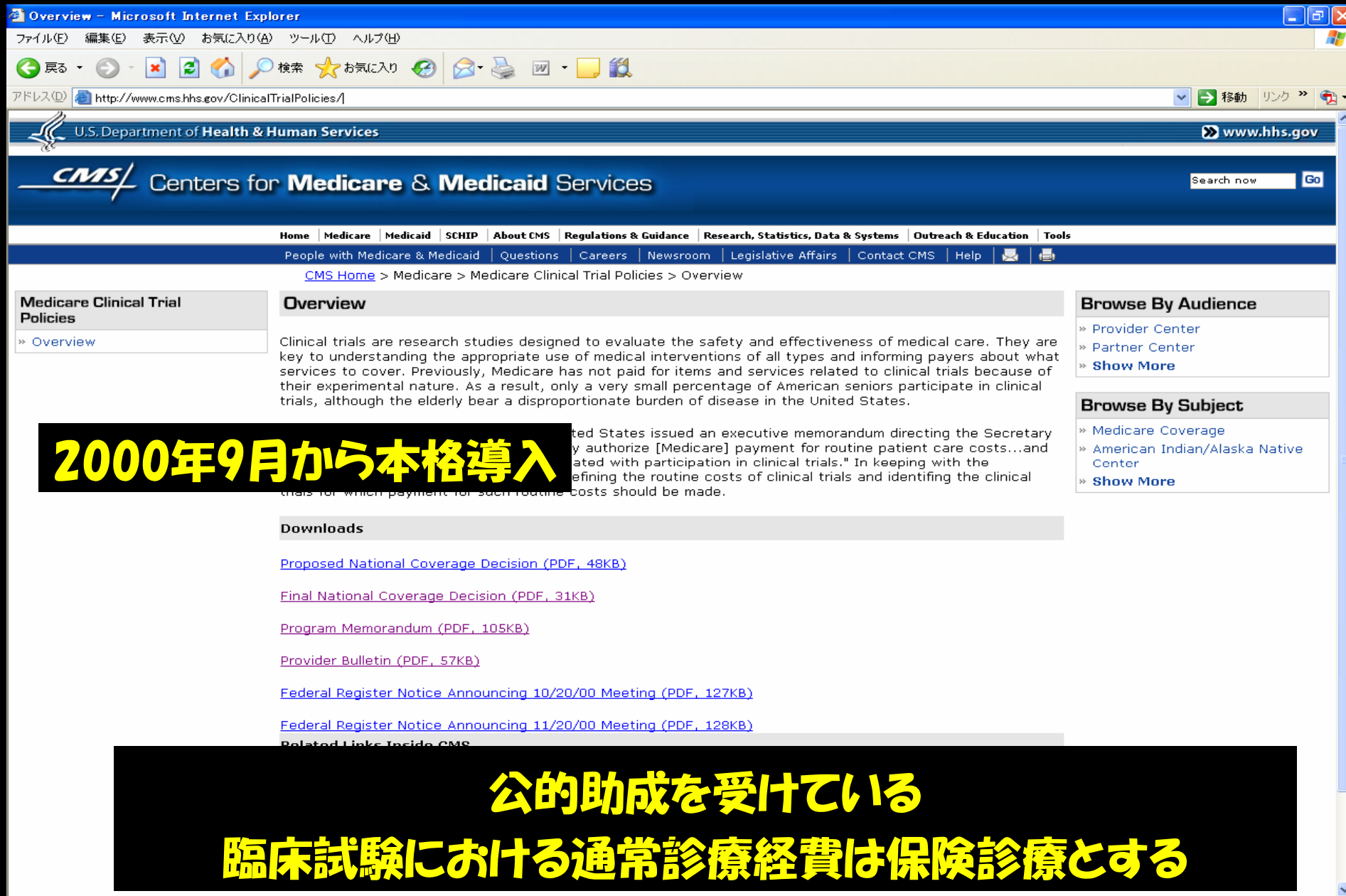
http://www.cms.hhs.gov/ClinicalTrialPolicies/



2000年9月から本格導入

公的助成を受けている
臨床試験における通常診療経費は保険診療とする

どのような臨床試験が対象となるのか

- **Deemed Trials.**

Some trials are considered automatically deemed as having desirable characteristics. They include:

Effective September 19, 2000

- **Trials funded by the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), CMS, Department of Defense (DOD), and Department of Veterans Affairs (VA);**

- **Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA;**

- **Trials conducted under an investigational new drug application (IND) reviewed by the Food and Drugs Administration (FDA);**

etc

Medicare Coverage Clinical Trial Program Memorandum

米国　臨床試験にかかるRoutine Cost とは

Routine costs DO include (and are therefore covered):

- **Items or services that are typically provided absent a clinical trial (e.g., medically necessary conventional care);**
- **Items and services required for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent),**
- **Items and services required for the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and**
- **Items and services that are medically necessary for the diagnosis or treatment of complications arising from the provision of an investigational item or service.**

Medicare Coverage Clinical Trial　Program Memorandum

Coverage with Evidence Development (CED)

http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1897