

heading of §413.184 to reflect that, as specified in the statute, this exception only pertains to a pediatric ESRD facility. However, this change was not made. Therefore, we proposed to revise the section heading of §413.184 to read as follows: "Payment exception: Pediatric patient mix."

We did not receive any comments regarding this proposal. Therefore, we are finalizing this provision as proposed.

4. Diagnostic X-Ray Tests, Diagnostic Laboratory Tests, and Other Diagnostic Tests: Conditions (§410.32(a)(1))

Section 1861(r)(5) of the Act was amended by section 4513(a) of the BBA to allow Medicare payment for a chiropractor's manual manipulation of the spine to correct subluxation, without requiring the subluxation to be demonstrated by an x-ray. The BBA provision was effective for services furnished on or after January 1, 2000. Prior to this statutory change, the subluxation was required to be demonstrated by an x-ray. Because chiropractors are limited by statute in the services they can provide under Medicare, it was necessary to create an exception to the requirement that diagnostic services (including x-rays) must be ordered by the treating physician as provided in §410.32(a). This exception, which permits a physician who

is not a treating physician to order and receive payment for an x-ray that is used by a chiropractor, is specified in §410.32(a)(1).

Because of the BBA change, which removed the requirement that subluxation must be demonstrated by an x-ray, the so-called "chiropractic exception" at §410.32(a)(1) is no longer warranted. We do not believe it is necessary or appropriate to continue to permit payment for an x-ray ordered by a nontreating physician when a chiropractor, not the ordering physician, will use that x-ray. Therefore, we proposed to revise §410.32 by removing paragraph (a)(1) and redesignating paragraphs (a)(2) and (a)(3) as (a)(1) and (a)(2), respectively.

Comment: We received several comments on this proposal. Some commenters noted that x-rays are not necessary to identify spinal subluxations, but stated that the ability to obtain an x-ray for Medicare beneficiaries is critical to providing responsible, safe, and medically prudent care. They stated that without this ability they fear beneficiaries and the chiropractic profession as a whole will be at a higher risk for receiving and providing the wrong type of care. The majority of commenters expressed concern that without the chiropractic exception at §410.32(a)(1), the beneficiary may incur greater

out-of-pocket expenses to obtain a noncovered x-ray when needed by the chiropractor. Other commenters believed that the overall costs for medical services may increase because a beneficiary wanting to seek chiropractic care directly may elect to first seek care for their condition from a medical doctor (MD) or doctor of osteopathy (DO) to obtain an order for a covered chiropractic x-ray, resulting in added costs for physician E/M services. Finally, many chiropractors commented that they are qualified to provide x-rays and other services that Medicare does not cover when furnished by a chiropractor and they believe that x-rays can be essential to rule out "red flags" and contraindications that may indicate the need for further diagnostic imaging or a referral to another health care professional.

Response: We believe that retaining the chiropractic exception would be inconsistent with the statutory provision at section 1861(r)(5) of the Act which defines a chiropractor as a physician only for the purposes of sections 1861(s)(1) and 1861(s)(2)(A) of the Act and only with respect to treatment by means of manual manipulation of the spine (that is, to correct a subluxation). This statutory provision does not include diagnostic services at section 1861(s)(3) of the Act, which is the benefit

category under which x-rays are covered under Medicare. In addition, commenters noted that x-rays are not required to identify subluxations; rather, commenters stated that they use the x-rays to rule out other conditions where manual manipulation of the spine would be contraindicated or for which further imaging studies are indicated. While the use of x-rays for this purpose is outside the scope of covered chiropractic services, it is also not addressed by the chiropractic exception at §410.32(a)(1). The chiropractic exception only permits a non-treating physician to order an x-ray to identify a subluxation. Therefore, we are finalizing our proposal to revise §410.32 by removing paragraph (a)(1) and redesignating paragraphs (a)(2) and (a)(3) as (a)(1) and (a)(2), respectively, so that it is consistent and conforms to the statutory revisions mandated by the BBA.

#### R. Other Issues

##### 1. Recalls and Replacement Devices

In the CY 2008 PFS proposed rule (72 FR 38191), we included a discussion about recent recalls of implantable cardioverter-defibrillator (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds). These recalls, as well as previous recalls of ICDs and pacemakers in CY 2004 and CY 2005, raise issues both with regard to