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CMS-3337-IFC
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 494

[CMS-3337-IFC]

RIN 0938-AT11

Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities--Third Party Payment

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period implements new requirements for Medicare-certified dialysis facilities that make payments of premiums for individual market health plans. These requirements apply to dialysis facilities that make such payments directly, through a parent organization, or through a third party. These requirements are intended to protect patient health and safety; improve patient disclosure and transparency; ensure that health insurance coverage decisions are not inappropriately influenced by the financial interests of dialysis facilities rather than the health and financial interests of patients; and protect patients from mid-year interruptions in coverage.

DATES: Effective date: These regulations are effective on [Insert date 30 days after the date of publication in the Federal Register].

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [Insert date 30 days after the date of filing for public inspection at OFR.]

ADDRESSES: In commenting, please refer to file code CMS-3337-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed)

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address **ONLY**:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-3337-IFC,
P.O. Box 8010,
Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address **ONLY**:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-3337-IFC,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW.,
Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786 9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY

INFORMATION" section.

FOR FURTHER INFORMATION CONTACT: Lauren Oviatt, (410) 786-4683, for issues related to the ESRD Conditions for Coverage.

Lina Rashid, (301) 492-4103, for issues related to individual market health plans.

SUPPLEMENTARY INFORMATION: Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Background

A. Statutory and Regulatory Background

1. End-Stage Renal Disease, Medicare, and Medicaid

End-Stage Renal Disease (ESRD) is a kidney impairment that is irreversible and permanent. Dialysis is a process for cleaning the blood and removing excess fluid artificially with special equipment when the kidneys have failed. People with ESRD require either a regular course of dialysis or kidney transplantation in order to live.

Given the high costs and absolute necessity of transplantation or dialysis for people with failed kidneys, Medicare provides health care coverage to qualifying individuals diagnosed with ESRD, regardless of age, including coverage for kidney transplantation, maintenance dialysis, and other health care needs. The ESRD benefit was established by the Social Security Amendments of 1972 (Pub. L. 92-603). This benefit is not a separate program, but allows qualifying individuals of any age to become Medicare beneficiaries and receive coverage. Under the statute, individuals under 65 who are entitled to Medicare through the ESRD program, or individuals over age 65 who are diagnosed with ESRD while in Original Medicare, generally cannot enroll in Medicare Advantage. Additionally, as access to Medigap policies is generally governed by state law, individuals under age 65 who are entitled to Medicare through the ESRD program cannot sign up for a Medigap policy in many States.¹

The ESRD Amendments of 1978 (Pub. L. 95-292), amended title XVIII of the Social Security Act (the Act) by adding section 1881 of the Act. Section 1881(b)(1) of the Act further authorizes the Secretary of the Department of Health and Human Services (the Secretary) to prescribe additional requirements (known as conditions for coverage or CfCs) that a facility providing dialysis and transplantation services to dialysis patients must meet to qualify for Medicare payment.

Medicare pays for routine maintenance dialysis provided by Medicare-certified ESRD facilities, also known as dialysis facilities. To gain certification, the State survey agency performs an on-site survey of the facility to determine if it meets the ESRD CfCs at 42 CFR part 494. If a survey indicates that a facility is in compliance with the conditions, and all other

¹ Medigap policies are available to people under age 65 with ESRD only in the following states: Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, New Hampshire, New Jersey, New York, North Carolina, Oklahoma, Oregon, Pennsylvania, South Dakota, Tennessee, Texas, Oklahoma, and Wisconsin.

Federal requirements are met, CMS then certifies the facility as qualifying for Medicare payment. Medicare payment for outpatient maintenance dialysis is limited to facilities meeting these conditions. The ESRD CfCs were first adopted in 1976 and comprehensively revised in 2008 (73 FR 20369). There are approximately 6,737 Medicare-certified dialysis facilities in the United States, providing dialysis services and specialized care to people with ESRD.

In addition to Medicare, Medicaid provides coverage for some people with ESRD. Many individuals enrolled in Medicare may also qualify for full benefits under the Medicaid program on the basis of their income, receipt of Supplemental Security Income, being determined medically-needy, or other eligibility categories under the State Plan. In addition, low income individuals enrolled in Medicare may qualify for the Medicare Savings Program under which the state's Medicaid program covers some or all of the individual's Medicare premiums and, for some individuals, Medicare cost-sharing. Finally, some individuals who are not eligible for enrollment in Medicare may qualify for Medicaid.

According to data published by the United States Renal Data System (USRDS), Medicare is the predominant payer of ESRD services in the United States, covering (as primary or secondary payer) about 88 percent of the United States ESRD patients receiving hemodialysis in 2014. Among those enrolled in Medicare on the basis of ESRD and receiving hemodialysis in 2015, CMS has determined 41 percent were enrolled in both Medicare and Medicaid (including full and partial duals). Among those enrolled in Medicare on the basis of ESRD under age 65, 51 percent were dual enrollees.

2. The Affordable Care Act and Health Insurance Exchanges

The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which

amended and revised several provisions of the Patient Protection and the Affordable Care Act, was enacted on March 30, 2010. In this interim final rule with comment, we refer to the two statutes collectively as the “Affordable Care Act.”

The Affordable Care Act reorganizes and amends the provisions of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The Affordable Care Act enacted a set of reforms to make health insurance coverage more affordable and accessible to millions of Americans. These reforms include the creation of competitive marketplaces called Affordable Insurance Exchanges, or “Exchanges” through which qualified individuals and qualified employers can purchase health insurance coverage.

In addition, many individuals who enroll in qualified health plans (QHPs) through individual market Exchanges are eligible for advance payments of the premium tax credit (APTC) to make health insurance premiums more affordable, and cost-sharing reduction (CSR) payments to reduce out-of-pocket expenses for health care services. Individuals enrolled in Medicare or Medicaid are not eligible for APTC or CSRs. The Affordable Care Act also established a risk adjustment program and other measures that are intended to mitigate the potential impact of adverse selection and stabilize the price of health insurance in the individual and small group markets.

The Public Health Service Act, as amended by the Affordable Care Act, generally prohibits group health plans and health insurance issuers offering group or individual health insurance coverage from imposing any preexisting condition exclusions. Health insurers can no longer charge different cost sharing or deny coverage to an individual because of a pre-existing health condition. Health insurance issuers also cannot limit benefits for that condition. The pre-

existing condition provision does not apply to “grandfathered” individual health insurance policies.

Beginning January 1, 2014, the Affordable Care Act prohibited insurers in the individual and group markets (with the exception of grandfathered individual plans) from imposing pre-existing condition exclusions. The Affordable Care Act’s prohibition on pre-existing condition exclusions enables consumers to access necessary benefits and services, beginning from their first day of coverage. The law also requires insurance companies to guarantee the availability and renewability of non-grandfathered health plans to any applicant regardless of his or her health status, subject to certain exceptions. It imposes rating restrictions on issuers prohibiting non-grandfathered individual and small group market insurance plans from varying premiums based on an individual’s health status. Issuers of such plans are now only allowed to vary premiums based on age, family size, geography, or tobacco use.

In previous rulemaking, CMS outlined major provisions and parameters related to many Affordable Care Act programs. This includes regulations at 45 CFR 156.1250, which require, among other things, that issuers offering individual market QHPs, including stand-alone dental plans, and their downstream entities, accept premium payments made on behalf of QHP enrollees from the following third party entities (in the case of a downstream entity, to the extent the entity routinely collects premiums or cost sharing): (1) a Ryan White HIV/AIDS Program under title XXVI of the PHS Act; (2) an Indian tribe, tribal organization, or urban Indian organization; and (3) a local, state, or Federal government program, including a grantee directed by a government program to make payments on its behalf. This regulation made clear that it did not prevent issuers from contractually prohibiting other third party payments. The regulation also reiterated that CMS discouraged premium payments and cost sharing assistance by certain

other entities, including hospitals and other health care providers, and discouraged issuers from accepting premium payments from such providers.² Regulations at 45 CFR 156.1240 require issuers offering individual market QHPs to accept payment from individuals in the form of paper checks, cashier's checks, money orders, EFT, and all general-purpose pre-paid debit cards. Regulations at 45 CFR 147.104 and 156.805 prohibit issuers from discriminating against or employing marketing practices that discriminate against individuals with significant health care needs.

3. Anti-Duplication

Individuals who are already covered by Medicare generally cannot become concurrently enrolled in coverage in the individual market. Section 1882(d)(3) of the Act makes it unlawful to sell or issue a health insurance policy (including policies issued on and off Exchanges) to an individual entitled to benefits under Medicare Part A or enrolled under Medicare part B with the knowledge that the policy duplicates the health benefits to which the individual is entitled. Therefore, while an individual with ESRD is not required to apply for and enroll in Medicare, once they become covered by Medicare it is unlawful for them to be sold a commercial health insurance policy in the individual market if the seller knows the individual market policy would duplicate benefits to which the individual is entitled.³ CMS has, moreover, solicited comments in a recent proposed rulemaking about whether it is unlawful in most or all cases to knowingly renew coverage under the same circumstances.⁴

2 Patient Protection and Affordable Care Act; Third Party Payment of Qualified Health Plan Premiums; Final Rule, 79 FR 15240 (March 14, 2014).

3 As discussed below, these anti-duplication standards—which govern the conduct of insurance companies, not health care providers-- have not prevented inappropriate steering of individuals eligible for Medicare to individual market plans

4 Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018; Proposed Rule, 81 FR 61455 (September 6, 2016).

4. HHS Request for Information on Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans

HHS has recently become concerned about the inappropriate “steering” of individuals eligible for or entitled to Medicare or Medicaid into individual market plans. In particular, HHS is concerned that because individual market health plans typically provide significantly greater reimbursement to health care providers than public coverage like Medicare or Medicaid, providers and suppliers may be engaged in practices designed to encourage individual patients to forego public coverage for which they are eligible and instead enroll in an individual market plan.⁵ In other words, health care providers may be encouraging individual patients to make coverage decisions based on the financial interest of the health care provider, rather than the best interests of the individual patient. Further, as one tool to influence these coverage decisions, health care providers may be offering to pay for, or arrange payment for, the premium for the individual market plan.

Based on these concerns, in August 2016, CMS issued a request for information (RFI), titled “Request for Information: Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans”, which published in the **Federal Register** on August 23, 2016, seeking comment from the public regarding concerns about health care providers and provider-affiliated organizations steering people into coverage that was of financial benefit to the provider, without regard to the impact on the patient (81 FR 57554). In response to this RFI, we received over 800 public comments by the comment closing date of September 22, 2016. Commenters included: patients; providers and provider-affiliated

⁵ Throughout this Interim Final Rule with Comment, the term “public coverage” is intended to refer to Medicare and Medicaid, not to a group health plan or health insurance purchased in the individual market in a state. A qualified health plan (QHP) purchased through an Exchange is individual market coverage, not public coverage.

organizations involved in the financing of care for patients; health insurance companies; social workers who are involved in counseling patients about potential health care coverage options; and other stakeholders. While commenters discussed patients with a variety of health care needs, the overwhelming majority of comments focused on patients with ESRD.

Comments indicated that dialysis facilities are involving themselves in ESRD patients' coverage decisions and that this practice is widespread. In addition, all commenters on the topic – including insurance companies, dialysis facilities, patients, and non-profit organizations – stated that they believe many dialysis facilities are paying for or arranging payments for individual market health care premiums for patients they serve.

Comments show that some ESRD patients are satisfied with their current premium arrangements. In particular, more than 600 individuals currently receiving assistance for premiums participated in a letter writing campaign in response to the RFI and stated that charitable premium assistance supports patient choice and is valuable to avoid relying on “taxpayer dollars.”

However, comments also documented a range of concerning practices, with providers and suppliers influencing enrollment decisions in ways that put the financial interest of the supplier above the needs of patients. As explained further below, commenters detailed that dialysis facilities benefit financially when individuals enroll in individual market health care coverage. Comments also described that, even though it is financially beneficial to suppliers, enrollment in individual market coverage paid for by dialysis facilities or organizations affiliated with dialysis facilities can lead to three types of harm to patients: negatively impacting their determination of readiness for a kidney transplant, potentially exposing patients to additional costs for health care services, and putting them at significant risk of a mid-year disruption in

health care coverage. Based on these comments, HHS has concluded that the differences between providers' and suppliers' financial interests and patients' interests may result in providers and suppliers taking actions that put patients' lives and wellbeing at risk.

B. Individual Market Coverage Is in the Financial Interest of Dialysis Facilities

All commenters who addressed the issue made clear that enrolling a patient in commercial coverage (including coverage in the individual market) rather than public coverage like Medicare and/or Medicaid is of significant financial benefit to dialysis facilities. For example, one comment cited reports from financial analysts estimating that commercial coverage generally pays dialysis facilities an average of four times more per treatment (\$1,000 per treatment in commercial coverage, compared to \$260 per treatment under public coverage). For a specific subset of individual market health plans – QHPs – the analysts estimated that the differential could be somewhat smaller, but that QHPs would still provide an average of an additional \$600 per treatment when compared to public coverage. Based on these reports, dialysis facilities would be estimated to be paid at least \$100,000 more per year per patient if a typical patient enrolled in commercial coverage rather than public coverage, despite providing the exact same services to patients. Another commenter estimated that a dialysis facility would earn an additional \$234,000 per year per patient by enrolling a patient in commercial coverage rather than Medicaid (\$312,000 per year rather than \$78,000 per year). A number of other commenters explained that commercial coverage reimburses dialysis facilities at significantly higher rates overall. These figures are consistent with other sources of data. For example, USRDS data show that for individuals with ESRD enrolled in Medicare receiving hemodialysis, health care spending averaged \$91,000 per individual in 2014, including dialysis and non-dialysis services. By contrast, using the Truven MarketScan database, a widely-used database of

health care claims, we estimate that average total spending for individuals with ESRD who are enrolled in commercial coverage was \$187,000 in 2014. In addition, recent filings with a federal court by one insurance company concluded that commercial coverage could pay more than ten times more per treatment than public coverage (\$4,000 per treatment rather than \$300 per treatment).⁶

As described, the comments in response to the RFI, data related to CMS's administration of the risk adjustment program, and registry data from the USRDS demonstrate that dialysis facilities can be paid tens or even hundreds of thousands of dollars more per patient when patients enroll in individual market coverage rather than public coverage. On the other hand, the premiums for enrollment in individual market coverage average \$4,200 per year according to data related to CMS's administration of the risk adjustment program. Dialysis facilities therefore have much to gain financially (on the order of tens or even hundreds of thousands of dollars per patient) by making a relatively small outlay to pay an individual's premium to enroll in commercial coverage so as to receive a much larger payment for providing an identical set of health care services. This asymmetry creates a strong financial incentive for such providers to use premium payments to steer as many patients as possible to commercial plans.

Commercial coverage pays at higher rates than public coverage for many health care services, and therefore this pattern could theoretically appear in a variety of contexts. Dialysis patients are, however, particularly vulnerable to harmful steering practices for a number of reasons. First, ESRD is the only health condition for which nearly all patients are eligible to apply for and enroll in Medicare coverage and with eligibility linked specifically to the

⁶ Davita encouraged some low-income patients to enroll in commercial plans; (Oct 23, 2016). http://www.stltoday.com/business/local/davita-encouraged-some-low-income-patients-to-enroll-in-commercial/article_ec5dc34e-ca4d-52e0-bc26-a3e56e1e2c85.html

diagnosis. Thus, individuals with ESRD face a unique situation where they have alternative public coverage options, but these coverage options may be less profitable from the perspective of the facilities providing their treatment due to lower reimbursement rates. Second, as described above, patients with ESRD must receive services from a dialysis facility several times per week for the remainder of their lives (unless and until they obtain a kidney transplant). This sort of ongoing receipt of specialized care from a particular facility is not typical of most health conditions and it creates especially strong incentives and opportunities for dialysis facilities to influence the coverage arrangements of the patients under their care.

C. Individual Market Coverage Supported by Third Parties Places Patients at Risk of Harm

Supporting premium payments to facilitate enrollment of their patients in individual market coverage is, as illustrated above, in the financial interest of the dialysis facilities. It is often not, however, in the best interests of individual patients. The comments in response to the RFI illustrated three types of potential harm to patients that these arrangements create for ESRD patients: negatively impacting patients' determination of readiness for a kidney transplant, potentially exposing patients to additional costs for health care services, and putting individuals at significant risk of a mid-year disruption in health care coverage.

While each of these potential harms is itself cause for concern, they collectively underscore the complexity of the decision for a patient with ESRD of choosing between coverage options, decisions that have very significant consequences for these patients in particular. The involvement of their providers in incentivizing, and steering them to enroll in, individual market coverage is highly problematic absent safeguards to ensure both that the individual is making a decision fully informed of these complex tradeoffs and that the risk of a

mid-year disruption in health care coverage is eliminated. Each of these specific potential harms to the patient is discussed further below.

1. Interference with Transplant Readiness

Access to kidney transplantation is a major and immediate concern for many patients with ESRD; transplantation is the recommended course of treatment for individuals with severe kidney disease, and is a life-saving treatment, as the risk of death for transplant recipients is less than half of that for dialysis patients. In addition to improving health outcomes, receipt of a transplant can dramatically improve patients' quality of life; instead of being required to undergo dialysis several times per week, individuals who have received transplants are able to resume a more typical pattern of daily life, travel, and employment. Of the approximately 700,000 people with ESRD in the United States, more than 100,000 are on formal waiting lists to receive a kidney transplant. Further, in 2015 more than 80 percent of kidney transplants went to patients under age 65, suggesting that transplantation is of special concern to nonelderly patients, who are most likely to be targeted by dialysis facilities for enrollment in individual market coverage because they may not already be enrolled in Medicare.

Therefore, any practice that interferes with patients' ability to pursue a kidney transplant is of significant concern. Even a small reduction in the likelihood of a patient receiving a transplant would be detrimental to a patient's health and wellbeing. The comments in response to the RFI support the conclusion that, today, enrollment in individual market coverage for which there are third party premium payments is hampering patients' ability to be determined ready for a kidney transplant. Comments make clear that, consistent with clinical guidelines, in order for a transplant center to determine that a patient is ready for a transplant, they must conclude that the individual will have access to continuous health care coverage. (This is necessary to ensure that

the patient will have ongoing access to necessary monitoring and follow-up care, and to immunosuppressant medications, which must typically be taken for the lifetime of a transplanted organ to prevent rejection.) However, when individuals with ESRD are enrolled in individual market coverage supported by third parties, they may have difficulty demonstrating continued access to care due to loss of premium support after transplantation. Documents in the comment record indicate that major non-profits that receive significant financial support from dialysis facilities will support payment of health insurance premiums only for patients currently receiving dialysis. Documents in the record show that these non-profits will not continue to provide financial assistance once a patient receives a successful kidney transplant, nor will the non-profit cover any costs of the transplant itself, living donor care, post-surgical care, post-transplant immunosuppressive therapy, or long-term monitoring, which can cause significant issues for patients that cannot afford their coverage without financial support. This policy is consistent with the conclusion that these third party payments are being targeted based on the financial interest of the dialysis facilities who contribute to these non-profits, rather than the patients' interests. Once a patient has received a transplant, it is no longer in the dialysis facility's financial interest to continue to support premium payments, although there are severe consequences to individuals when that support ceases. If this occurs after transplantation, individuals enrolled in individual market coverage could be required to pay the full amount of the premium, which may be unaffordable for many patients who previously relied on third party premium assistance.

Theoretically, individuals could arrange for Medicare coverage to begin at the time of transplantation, thereby demonstrating continued access to care. In practice, however, patients struggle to understand their coverage options and rapidly navigate the Medicare sign-up process

during a period where they are particularly sick and preparing for major surgery. Some commenters to the RFI emphasized that this is an extremely vulnerable group of patients who have difficulty navigating their health insurance options. As evidenced by the rate of dually eligible individuals discussed above, many ESRD patients are low income and have limited access to the resources necessary to navigate these sorts of coverage transitions, and patients are particularly vulnerable during the short window when they are preparing for transplants.

Consistent with this, a number of comments describe how these arrangements and patients' vulnerability and confusion about alternative coverage both pre- and post-transplant have in fact interfered with patients' care. For example, one comment describes a family that was trying to obtain a transplant for a young child that had to arrange other coverage on an emergency basis to obtain their child's transplant. The family had allegedly been given inaccurate information by a dialysis facility about their coverage options and how private health insurance and Medicare would affect their child's transplant. Another commenter employed by a transplant facility described that "many" patients in individual market plans had "their transplant evaluations discontinued or delayed while they worked to obtain appropriate and affordable insurance coverage." A number of other social workers who submitted comments in response to the RFI also identified these transplant access issues as a major concern.

2. Exposure to Additional Costs for Health Care Services

In addition to impeding access to transplants, enrollment in individual market coverage, even when third parties cover costs, is financially disadvantageous for some patients with ESRD. That is, while it is in dialysis facilities' financial interest to support enrollment in the individual market, those arrangements may cause financial harms to patients that would have been avoided had the patients instead enrolled in public coverage.

People with ESRD often have complex needs and receive care from a wide variety of health care providers and suppliers. Data from USRDS show that total health care spending per Medicare ESRD enrollee receiving hemodialysis averaged more than \$91,000 in 2014, but spending on hemodialysis is only 32 percent of that amount, meaning that a typical patient may incur thousands of dollars in costs for other services. While some of the non-dialysis services these patients receive may also be provided by their dialysis facilities, half or more of Medicare spending on this population is for care that is likely delivered by other providers and suppliers, including creation and maintenance of vascular access, inpatient hospital care, skilled nursing facility services, home health services, palliative services, ambulance services, treatment for primary care and comorbid conditions, and prescription drugs. Thus, when considering the financial impact of coverage decisions, it is important to consider costs that a patient will incur for services received that go beyond dialysis.

a. Eligibility for Medicaid

As described above, many people with ESRD are eligible for Medicaid. Indeed, more than half of ESRD Medicare enrollees under age 65 are also enrolled in Medicaid.⁷ For many Medicaid enrollees, the health care costs for which they are financially responsible are negligible – and many face no cost-sharing or premiums at all. By contrast, consumers in the individual market were responsible for out-of-pocket costs up to \$7,150 in 2017⁸. As described above, much of that out-of-pocket exposure is likely to be incurred outside of the dialysis facility so, even if a provider or non-profit covers out-of-pocket costs related to dialysis, enrolling in an individual market plan rather than Medicaid exposes very-low income patients to thousands of

⁷ This figure includes both individuals who are fully enrolled in Medicare and Medicaid, and individuals enrolled in Medicare and the Medicare Saving Program.

⁸ Patient Protection and Affordable Care Act; HHS Notice of Payment and Benefit Parameters for 2017, (March 8, 2016); <https://www.gpo.gov/fdsys/pkg/FR-2016-09-06/pdf/2016-20896.pdf>

dollars in out-of-pocket costs.⁹ Indeed, given the Medicaid income limits, this cost-sharing is likely to be an extraordinarily large fraction of their income. Further, Medicaid includes coverage for services not likely to be covered by individual market plans, such as non-emergency medical transportation (which can vary based on the state or type of Medicaid coverage), and patients will forego these benefits if they instead enroll in the individual market. It is possible for an individual to be enrolled in both Medicaid and individual market coverage,¹⁰ and Medicaid would, in theory, wrap around the individual market plan. Such an arrangement would be of great financial benefit to the dialysis facility, but would be unlikely to provide financial benefits to the individual (because the individual's cost sharing and benefits would often be the same as if they had enrolled only in Medicaid). Moreover, in practice, this arrangement creates a significant financial risk for low-income individuals, who will need to coordinate multiple types of coverage or else could find themselves receiving large bills from health care providers and suppliers not aware of their Medicaid coverage. Thus, it is very unlikely that it would be in such individual's financial interest to elect individual market coverage.

b. Eligible for Medicare but not Medicaid

For individuals with ESRD not eligible for Medicaid, enrolling in the individual market rather than Medicare may also pose significant financial risks. As noted above, these patients generally require access to a wide variety of services received outside of a dialysis facility.

Patients with ESRD are generally enrolled in Original Medicare (including Part A and Part B) and can therefore receive services from any Medicare-participating provider or supplier.

⁹ Because these individuals are eligible for Medicaid, they are generally prohibited from receiving cost-sharing reductions for enrolling in coverage through an Exchange.

¹⁰ No APTC or CSR would be available to support enrollment in the individual market in this circumstance.

However, unlike Original Medicare, which provides access to a wide range of eligible providers and suppliers, and which has standard cost-sharing requirements for all Medicare-eligible providers and suppliers, individual market plans generally limit access to a set network of providers that is more restrictive than what is available to an Original Medicare beneficiary. If the individual sees providers or suppliers outside of that network, they will incur higher cost-sharing for necessary out-of-network services, and may have very limited coverage for non-emergency out-of-network health care.

There may be other personal circumstances that lead to financial burden caused by enrolling in an individual market plan rather than Medicare. For example, individuals who are entitled to Part A and do not enroll in Part B generally will incur a Part B late enrollment penalty when they do ultimately enroll in Medicare Part B. Accordingly, an individual who enrolls in Part A based on ESRD but does not enroll in or drops Part B will generally be subject to a late enrollment penalty should they decide to enroll in Part B later while still entitled to Part A on the basis of ESRD. Individuals who receive a kidney transplant may also face higher cost-sharing for immunosuppressant drugs if they delay Medicare enrollment as immunosuppressive drugs are covered under Part B only if the transplant recipient established Part A effective with the month of the transplant.

As noted above, for some members of this group, there is potentially an offsetting financial benefit from individual market coverage if total premiums and cost sharing are lower in an individual market plan with third party premium assistance than in Medicare. In particular, non-grandfathered individual markets plans are required to cap total annual out-of-pocket expenditures for essential health benefits at a fixed amount, the maximum out-of-pocket limit, which is \$7,150 in 2017. The individual may not be able to cap their annual out-of-pocket

expenses in Medicare; while individuals over age 65 are eligible to enroll in Medicare Advantage or Medigap supplemental plans, which do cap annual expenses, individuals under age 65 with ESRD generally do not have such options in many states.¹¹ However, third party assistance is also frequently available to offset out-of-pocket costs for Medicare enrollees. Moreover, if dialysis facilities were not providing assistance for individual market coverage on such a widespread basis, they might use these resources to make assistance for out-of-pocket Medicare costs even more widely available.

3. Risks of Mid-Year Disruption in Coverage

Finally, the comments in response to the RFI demonstrate that there is a significant risk of mid-year disruptions in coverage for patients/individuals who have individual market coverage for which third parties make premium payments. It is critically important that patients on dialysis have continuous access to health care coverage. Prior to transplantation this population requires an expensive health care service several times per week in order to live; any interruption in their access to care is serious and life-threatening. Moreover, as noted, this group generally has health care needs beyond dialysis that require care from a variety of medical professionals.

However, the comments reveal that patients/individuals who have individual market coverage for which third parties make premium payments are presently at risk of having their coverage disrupted at any point during the year. CMS does not require that issuers accept premium payments made by third parties except in certain circumstances consistent with applicable legal requirements,¹² and CMS has consistently discouraged issuers from accepting

¹¹ Congress recently passed legislation that would allow people enrolled in Medicare on the basis of ESRD to select a Medicare Advantage plan beginning in 2021.

¹² 45 CFR 156.1250 requires issuers to accept third party payment from federal, state and local government

payments directly from health care providers.¹³ Many issuers have provisions in their contracts with enrollees that are intended to void the contract if payment is made by someone other than the enrollee. Issuers that provided comments in response to the RFI confirmed that they do not accept certain third party payments. One comment included a list of ten states where major issuers are known to reject these payments when identified. Comments from health care providers and non-profits described that entities that make third party payments to issuers have attempted to disguise their payments to circumvent detection by issuers. These comments also described how issuers are increasingly monitoring for and seeking to identify third party payments, and when issuers discover those payments, they are rejected. The lack of transparency around third party payments has therefore resulted in a situation in which patients are at significant and ongoing risk of losing access to coverage based on their issuer detecting payment of their premiums by parties other than the enrollee.

When payments are rejected, commenters noted that individuals are typically unable to continue their coverage because of the increased financial burden. Indeed, patients may not even realize for some period that their premiums, which are being paid by third parties, are being rejected and that their coverage will be terminated if they do not have an ability to pay themselves. HHS received 600 comments from ESRD patients participating in a letter-writing campaign that describe the adverse impact on patients receiving third party payment premium assistance if those funds were no longer available. Other patients who commented described significant and unexpected disruptions in coverage such as no longer being able to afford the high cost of prescriptions and office visit copays, delays receiving dialysis treatments, or no

programs, Ryan White/HIV Aids Programs and Indian Tribes, Tribal Organizations, and Urban Indian Organizations.

13 Third Party Payments of Premiums for Qualified Health Plans in the Marketplaces, November 4, 2013, <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-qa-11-04-2013.pdf>

longer being able to receive treatments. Due to the life-sustaining nature of dialysis, dialysis facilities are not permitted to involuntarily discharge patients, except in very limited circumstances. However, one of those circumstances is lack of payment (42 CFR 494.180 (f)(1)). While we believe that such discharges are rare, and that dialysis facilities try to avoid them, they are permitted. Moreover, even when patients are able to enroll in other public coverage (which may have retroactive effective dates) disruptions in coverage still force patients to navigate a complicated set of coverage options. They may face gaps in care or be forced to appeal health care claims. Comments emphasized that many ESRD patients are low-income and do not have a great deal of familiarity with the health care system, leaving them more vulnerable to gaps in coverage. Therefore, any disruption in coverage is problematic and can interrupt patient care.

In sum, the lack of transparency in how these payments are made and whether or not they are accepted means that patients are at risk of sudden gaps in coverage which may be dangerous to patients' health.

D. Conflict Between Dialysis Facilities' Financial Interest and Patients' Interest Has Led to Problematic Steering

As described above, dialysis facilities have very meaningful financial incentives to have their patients enroll in individual market coverage rather than public coverage programs. However, enrollments in individual market coverage are often not in patients' best interest: it can complicate and potentially delay the process for obtaining a kidney transplant; is often financially costly for patients, especially when they are eligible for Medicaid; and places consumers at risk of a mid-year coverage disruption. These risks make the task of deciding among coverage options complex for ESRD patients. Furthermore, the asymmetry between

facilities' and patients' interests and information with respect to enrollment decisions creates a high likelihood that a conflict of interest will develop. Comments submitted in response to the RFI support the conclusion that this conflict of interest is harming patients, with dialysis facility patients being steered toward enrollment in individual market coverage with third party premium payments, rather than enrollment in the public coverage for which they are likely eligible and which is frequently the better coverage option for them.

Many comments were submitted by social workers or other professionals who work or have worked with ESRD patients. Those comments describe a variety of ways in which dialysis facilities have attempted to influence coverage decisions made by patients or have failed to disclose information that is relevant to determining consumers' best interest. Specific practices described in comments include:

- Facilities engaging in systematic efforts to enroll people in the individual market, often targeting Medicaid enrollees, without assessing any personal needs. One commenter explained, "My experience was that the provider wanted anyone [who] was Medicaid only to be educated about the opportunity to apply for an individual plan.... The goal was 100% education, whether there was an assessed need or not.... Valuable hours of professional interventions were taken from direct patient care concerns and diverted to this." Another explained, "There was a list of all Medicaid patients and the insurance management team was responsible for documenting why the patient did not switch to an individual market plan." Comments also described cases in

which social worker compensation was linked to enrolling patients in individual market coverage.

- Patients are not always informed about eligibility for Medicare or Medicaid, or the benefits of those programs. For example, one social worker explained, "The patient is frequently not educated about the benefits that are available with Medicaid (that is, transportation, dental, and other home support services)." Another former social worker said that facility employees "may not tell patients that they could be subject to premium penalties and potentially higher out-of-pocket costs than they would have with traditional Medicare." Another commenter said, "Enrollment counselors offer no information about Medicare eligibility to members. In several cases members were not aware that they were Medicare eligible."
- Patients are sometimes specifically discouraged from pursuing Medicare or Medicaid. One commenter said: "In the transplant setting I have seen patients advised to delay in securing Medicare." Another employee at a dialysis facility relayed the story of a mother seeking a transplant for her daughter but being told by a dialysis facility not to enroll in Medicare. A transplant facility employee explained "In some circumstances, the patient has been encouraged to drop their MediCal (Medicaid) coverage

in favor of the individual market plan, without having a full understanding of the personal financial impact of doing so.”

- Patients are unaware that a dialysis facility is seeking to enroll them in the individual market and are not informed of this fact by their health care providers. As one commenter said, “In numerous instances, these patients were already admitted at these facilities, and interviews have found that many were unaware they had insurance, let alone who was providing it.”
- Patients are not informed about how their third party premium support is linked to continued receipt of dialysis. For example, one comment explained, “People receiving assistance don't realize that if they want a transplant the premiums will no longer get paid.”
- Facilities retaliate against social workers who attempt to disclose additional information to consumers. One commenter explained that they were “reported to upper management of [dialysis corporations] for voicing my concerns of the impact this [enrollment in the individual market] will have on patients after transplant.”
- Social workers are concerned that patients’ trust in health care providers is being manipulated to facilitate individual market enrollment. For example, comments

explained that insurance counselors “meet often with the patients establishing a relationship of trust” before pursuing individual market enrollment. A commenter said, “Most of us, who have some sophistication in health care coverage, are aware of how confusing it is to negotiate the information and reach the best decisions. Dialysis patients who may be less sophisticated and already highly stressed are vulnerable to being steered.” Another commenter vividly explained, “Patients... are in a vulnerable position when they come to a dialysis facility. I hope those of you reviewing these comments realize the power disequilibrium which exists when a patient is hooked up with needles in their arm, lifeblood running through their arms attached to a machine.”

In addition, HHS's own data and information submitted in response to the RFI suggest that this inappropriate steering of patients may be accelerating over time. Insurance industry commenters stated that the number of enrollees in individual market plans receiving dialysis increased 2 to 5 fold in recent years. Based on concerns raised in the public comments in response to the RFI, we have reviewed administrative data on enrollment of patients with ESRD. Information available from the risk adjustment program in the individual market show that between 2014 and 2015, the number of individual market enrollees with an ESRD diagnosis more than doubled.¹⁴ In some states increases were more rapid, with some states seeing more than five times as many patients with ESRD in the individual market in 2015 as in 2014. While increased enrollment in the individual market among individuals who have ESRD is not in itself evidence of inappropriate provider or supplier behavior, these changes in enrollment patterns raise concerns that the steering behavior commenters described may be becoming increasingly common over time.

E. HHS Is Taking Immediate Regulatory Action To Protect Patients

In the face of harms like those above, which go to essential patient safety and care in life-threatening circumstances, HHS is taking immediate regulatory action to prevent harms to patients. As described in more detail below, we are establishing new Conditions for Coverage standards (CfCs) for dialysis facilities. This standard applies to any dialysis facility that makes payments of premiums for individual market health plans (in any amount), whether directly, through a parent organization (such as a dialysis corporation), or through another entity (including by providing contributions to entities that make such payments). Dialysis facilities subject to the new standard will be required to make patients aware of potential coverage options

¹⁴ Risk adjustment applies to the entire individual market, including plans offered on and off an Exchange.

and educate them about the benefits of each to improve transparency for consumers. Further, in order to ensure that patients' coverage is not disrupted mid-year, facilities must ensure that issuers are informed of and have agreed to accept the payments.¹⁵

This action is consistent with comments from dialysis facilities, non-profits, social workers, and issuers that generally emphasized disclosure and transparency as important components of a potential rulemaking. By focusing on transparency, we believe we can promote patients' best interests. CMS remains concerned, however, about the extent of the abuses reported. We are considering whether it would be appropriate to prohibit third party premium payments for individual market coverage completely for people with alternative public coverage. Given the magnitude of the potential financial conflict of interest and the abusive practices described above, we are unsure if disclosure standards will be sufficient to protect patients. We seek comments from stakeholders on whether patients would be better off if premium payments in this context were more strictly limited. We also seek comment on alternative options where payments would be prohibited absent a showing that a third party payment was in the individual's best interest, and we seek comment on what such a showing would require and how it could prevent mid-year disruptions in coverage.

II. Provisions of the Interim Final Rule

Through this Interim Final Rule with comment (IFC) we are implementing a number of disclosure requirements for dialysis facilities that make payments of premiums for individual market health plans, whether directly, through a parent organization, or through another entity, to

¹⁵ There are two potential ways to prevent mid-year disruptions in coverage – either requiring issuers to accept these payments or requiring facilities to disclose them and assure acceptance. Both would equally promote continuity of coverage for consumers. However, requiring issuers to accept payments in these circumstances would destabilize the individual market risk pool, a position CMS has consistently articulated since 2013, when we expressly discouraged issuers from accepting these third party payments from providers. The underlying policy considerations have not changed and therefore CMS is seeking to prevent mid-year disruption by requiring facilities to disclose payments and assure acceptance.

ensure proper protections for those patients. These requirements are intended to ensure that patients are able to make insurance coverage decisions based on full and accurate information.

As described in more detail below, we are establishing new CfC standards for dialysis facilities. New standards apply to any dialysis facility that makes payments of premiums for individual market health plans (in any amount), whether directly, through a parent organization (such as a dialysis corporation), or through another entity (including by providing contributions to entities that make such payments). While we remain concerned about any type of financial assistance that could be used to influence patients' coverage decisions, we believe these individual market premium payments are particularly prone to abuse because they are so closely tied to the type of coverage an individual selects. Further, as described above, such third party payments in the individual market uniquely put patients at risk of mid-year coverage disruption if their issuer discovers and rejects such payments. Dialysis facilities subject to the new standards will be required to make patients aware of potential coverage options and educate them about certain benefits and risks of each. Further, in order to ensure that patients' coverage is not disrupted mid-year, dialysis facilities must ensure that issuers are informed of and have agreed to accept such payments for the duration of the plan year.

A. Disclosures to Consumers: Patients' Right to be Informed of Coverage Options and Third Party Premium Payments (42 CFR 494.70(c))

In order to increase awareness of health coverage options for individuals receiving maintenance dialysis in Medicare-certified dialysis facilities, we are establishing a new patient rights standard under the CfCs at 42 CFR 494.70(c). This new standard applies only to those facilities that make payments of premiums for individual market health plans (in any amount),

whether directly, through a parent organization (such as a dialysis corporation), or through another entity (including by providing contributions to entities that make such payments).

Dialysis facilities that do not make premium payments, and do not make financial contributions to other entities that make such payments, are not subject to the new requirements.¹⁶ We recognize that dialysis facilities make charitable contributions to a variety of groups and causes. This rule applies only to those dialysis facilities that make payments of premiums for individual market health plans, whether directly, through a parent organization, or through another entity.

At § 494.70 (c)(1), we detail the health insurance information that must be provided to all patients served by applicable facilities. These requirements establish that such information must cover how plans in the individual market will affect the patient's access to and costs for the providers and suppliers, services, and prescription drugs that are currently within the individual's care plan, as well as those likely to result from other documented health care needs. This must include an overview of the health-related and financial risks and benefits of the individual market plans available to the patient (including plans offered through and outside the Exchange). This information must reflect local, current plans, and thus would need to be updated at least annually to reflect changes to individual market plans. We expect that applicable dialysis facilities will

¹⁶ A facility that makes payments of premiums for individual market coverage of its patients must comply with this standard. Similarly, a facility that makes a financial contribution to another organization, that is able to use the funds to make payments of premiums for individual market coverage of some dialysis patients must also comply, even when the contributions from the facility are not directly linked to the premium payments; we note, moreover, that mere recitation on a check that a contribution cannot be used for premium payments would not establish that an organization is unable to use the contribution for such payments. Further, an entity that makes contributions through a third party that in turn contributes to an entity that is able to use the contribution to make third party premium payments will still be subject to these standards. In contrast, a facility that does not make payments of premiums for individual market coverage and does not contribute to any organization that makes such payments, but does contribute to an organization that supports premiums for Medicare enrollment, would not be required to comply with this standard.

meet this requirement by providing the required information upon an individual's admittance to the facility, and annually thereafter, on a timely basis for each plan year.

While current costs to the patient are important, information about potential future costs related to the current health plan selection must also be addressed. In particular, we are requiring that coverage of transplantation and associated transplant costs must be included in information provided to patients. For example, some plans may not cover all costs typically covered by Medicare, such as necessary medical expenses for living donors. Kidney transplant patients who want Medicare to cover immunosuppressive drugs must have Part A at the time of the kidney transplant. Upon enrolling in Part B, Medicare will generally cover the immunosuppressive drugs. Therefore, the beneficiary must file for Part A no later than the 12th month after the month of the kidney transplant. Entitlement to Part A and Part B based on a kidney transplant terminates 36 months after the transplant. However, a beneficiary who establishes Part A entitlement effective with the month of the transplant is eligible for immunosuppressive drug coverage when subsequent entitlement to Part B is based on age or disability. Facilities must provide information regarding enrollment in Medicare, and clearly explain Medicare's benefits to the patient. Facilities must also provide individuals with information about Medicaid, including State eligibility requirements, and if there is any reason to believe the patient may be eligible, clearly explain the State's Medicaid benefits, including the Medicare Savings Programs.

For other potential future effects, the facilities must provide information about penalties associated with late enrollment (or re-enrollment) in Medicare Part B or Part D for those that have Medicare Part A as well as potential delays or gaps in coverage. Section 1839(b) of the Act outlines the Medicare premium-Part A (for those who are not eligible for premium-free Part A) and Part B late enrollment penalty. Individuals who do not enroll in Medicare premium-Part A

or Medicare Part B when first eligible (that is, during their Initial Enrollment Period) will have to pay a late enrollment penalty should they decide to enroll at a later time. There are certain circumstances in which individuals are exempt from the late enrollment penalty, such as those who are eligible for Medicare based on Age or Disability, and did not enroll when first eligible because they had or have group health plan coverage based on their own or spouse's (or a family member if Medicare is based on disability) current employment.

Although an ESRD diagnosis may establish eligibility for Medicare regardless of age, it does not make individuals eligible for a Medicare Special Enrollment Period or provide relief from the late enrollment penalty. Thus, if an individual enrolls in Medicare Part A but does not enroll in Part B, or later drops Part B coverage, that individual will pay a Part B (and Part D) late enrollment penalty when ultimately enrolling, or reenrolling, in Medicare Part B (and Part D). Additionally, that individual will need to wait until the Medicare General Enrollment Period to apply for Medicare Part B. The General Enrollment Period runs from January 1 to March 31 each year, and Part B coverage becomes effective July 1 of the same year. Thus, individuals could face significant gaps in coverage while waiting for their Medicare Part B coverage to become effective. We note that late enrollment penalties and statutory enrollment periods do not apply to premium-free Part A.

Information about potential costs to the patient is vitally important for patients considering individual market coverage. An individual may benefit in the short term by selecting a private health plan instead of enrolling in Medicare, but patients must be informed that those plans, or the particular costs and benefits of those plans, may only exist for a given plan year, and that the individual may be at a disadvantage (that is, late enrollment penalties for

those that are enrolled in Medicare Part A) should they choose to enroll in Medicare Part B (or Part D) at a later date.

At § 494.70(c)(2) and (3), we require that applicable facilities provide information to all patients about available premium payments for individual market plans and the nature of the facility's or parent organization's contributions to such efforts and programs. This information must include, but is not limited to, limits on financial assistance and other information important for the patient to make an informed decision, including the reimbursements for services rendered that the facility would receive from each coverage option. For example, if premium payments are not guaranteed for an entire plan year, or funding is capped at a certain dollar amount, patients must be informed of such limits. Facilities also must inform patients if the premium payments are contingent on continued use of dialysis services or use of a particular facility, and would therefore be terminated in the event that the patient receives a successful kidney transplant or transfers to a different dialysis facility. Further, facilities must disclose to patients all aggregate amounts that support enrollment in individual market health plans provided to patients directly, to issuers directly, through the facility's parent organization, or through third parties.

As with all patient rights standards for dialysis facilities, the information and disclosures required in § 494.70(c) must be provided to all patients of applicable facilities, not just those new to a facility who have not yet enrolled in Medicare or Medicaid. This ensures that all patients are treated fairly and appropriately, and not treated differently based on their health care payer, as required by CMS regulations at 42 CFR 489.53(a)(2).

B. Disclosures to Issuers (42 CFR 494.180(k))

In conjunction with these requirements for patient information and disclosures, we establish at § 494.180(k), a new standard that requires facilities that make payments of premiums

for individual market health plans, whether directly, through a parent organization, or through another entity to ensure that issuers are informed of and have agreed to accept the third party payments. Facilities should develop reasonable procedures for communicating with health insurance issuers in the individual market, and for obtaining and documenting that the issuer has agreed to accept such payments. If an issuer does not agree to accept the payments for the duration of the plan year, the facility shall not make payments of premiums and shall take reasonable steps to ensure that such payments are not made by any third parties to which the facility contributes.

These requirements are intended to protect ESRD patients from avoidable interruptions in health insurance coverage mid-year by ensuring that they have access to full, accurate information about health coverage options. We intend to outline expectations for compliance in subsequent guidance. This rule does not alter the legal obligations or requirements placed on issuers, including with respect to the guaranteed availability and renewability requirements of the Public Health Service Act and non-discrimination-related regulations issued pursuant to the Affordable Care Act.¹⁷

C. Effective Date

Because we are concerned that patients face risks that are not disclosed to them, and that they may be at risk of disruptions in coverage on an ongoing basis, we are taking action to ensure greater disclosure to consumers and to provide for smooth and continuous access to stable coverage when these rules are fully implemented. At the same time, we are mindful of the need for dialysis facilities that make payments of premiums for individual market health plans, whether directly, through a parent organization, or through another entity, to develop new

¹⁷ See 45 CFR 147.104, 156.225, 156.805.

procedures to comply with the standards established in this rule. Therefore, the requirements in this rule will become effective beginning [Insert date 30 days after the date of publication in the **Federal Register**].

We note that, in specific circumstances, individuals may not be eligible to enroll in Medicare Part A or Part B except during the General Enrollment Period, which runs from January 1 to March 31 and after which coverage becomes effective on July 1. These individuals may experience a temporary disruption in coverage between the effective date of the rule and the time when Medicare Part A and/or Part B coverage becomes effective. In light of these circumstances, while the standards under § 494.180(k) will be effective beginning [Insert date 30 days after the date of publication in the **Federal Register**], if a facility is aware of a patient who is not eligible for Medicaid and is not eligible to enroll in Medicare Part A and/or Part B except during the General Enrollment Period, and the facility is aware that the patient intends to enroll in Medicare Part A and/or Part B during that period, the standards under § 494.180(k) will not apply until July 1, 2017, with respect to payments made for that patient.

III. Waiver of Proposed Rulemaking and Delay in Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule in accordance with 5 U.S.C. 553(b) of the Administrative Procedure Act (APA) and section 1871(b)(1) of the Social Security Act. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

HHS has determined that issuing this regulation as a proposed rulemaking, such that it would not become effective until after public comments are submitted, considered and responded to in a final rule, would be contrary to the public interest and would cause harm to patients. Based on the newly available evidence discussed in section I of this rule, that is, the responses to the August 2016 RFI, HHS has determined that the widespread practice of third parties making payments of premiums for individual market coverage places dialysis patients at significant risk of three kinds of harms: having their ability to be determined ready for a kidney transplant negatively affected, being exposed to additional costs for health care services, and being exposed to a significant risk of a mid-year disruption in health care coverage. We believe these are unacceptable risks to patient health that will be greatly mitigated by this rulemaking, and that the delay caused by notice and comment rulemaking would continue to put patient health at risk. Given the risk of patient harm, notice and comment rulemaking would be contrary to the public interest. Therefore, we find good cause to waive notice and comment rulemaking and to issue this interim final rule with comment. We are providing a 30-day public comment period.

In addition, we ordinarily provide a 60-day delay in the effective date of the provisions of a rule in accordance with the APA (5 U.S.C. 553(d)), which requires a 30-day delayed effective date, and the Congressional Review Act (5 U.S.C. 801(a)(3)), which requires a 60-day delayed effective date for major rules. However, we can waive the delay in the effective date if the Secretary finds, for good cause, that the delay is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons in the rule issued (5 U.S.C. 553(d)(3) .

In addition, the Congressional Review Act (5 U.S.C. 801(a)(3)) requires a 60-day delayed effective date for major rules. However, we can determine the effective date of the rule

if the Secretary finds, for good cause, that notice and public procedure is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons in the rule issued (5 U.S.C. 808(2)).

As noted above, for good cause, we have found that notice and public procedure is contrary to the public interest. Accordingly, we have determined that it is appropriate to issue this regulation with an effective date 30 days from the date of publication. As described above, we believe patients are currently at risk of harm. Health-related and financial risks are not fully disclosed to them, and they may have their transplant readiness delayed or face additional financial consequences because of coverage decisions that are not fully explained. Further, consumers are at risk of mid-year coverage disruptions. This is the time of year when patients often make enrollment decisions, with Open Enrollment in the individual market ongoing and General Enrollment Period for certain new enrollees in Medicare about to begin on January 1. We have therefore determined that the rule will become effective on [insert date 30 days from publication] to best protect consumers.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. This interim final rule with comment contains information collection requirements (ICRs) that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 1. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A)

of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of the interim final rule with comment that contain ICRs. We generally used data from the Bureau of Labor Statistics to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with the ICRs.¹⁸

1. ICRs Regarding Patient Rights (§ 494.70(c))

Under § 494.70(c), HHS implements a number of requirements and establishes a new patient rights standard for Medicare-certified dialysis facilities that make payments of premiums for individual market health plans, whether directly, through a parent organization, or through another entity, to ensure proper protections for those patients. Those applicable facilities will be required, on an annual basis, to inform patients of health coverage options available to them, including Medicare and Medicaid and locally available individual market plans; enrollment periods for both Medicare and the individual market; the effects each option will have on the patients access to, and costs for the providers and suppliers, services, and prescription drugs that

¹⁸ See May 2015 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates at http://www.bls.gov/oes/current/oes_stru.htm.

are currently within the individual's ESRD plan of care and other documented health care needs; coverage and anticipated costs for transplant services, including pre- and post- transplant care; any funds available to the patient for enrollment in an individual market health plan, including but not limited to limitations and any associated risks of such assistance; and current information about the facility's, or its parent organization's premium payments for patients, or to other third parties that make such premium payments to individual market health plans for individuals on dialysis.

We assume that each applicable facility will develop a system to educate and inform each ESRD patient of their options and the effects of these options. For our purposes, we assume that each facility will develop a pamphlet containing information that compares the benefits and costs for each locally available individual market plan, Medicare, and Medicaid, and display it prominently in their facility. In addition, it is assumed that a facility staff such as a health care social worker will review the required information with the patient and answer any questions.

There are 6,737 Medicare-certified dialysis facilities. As explained later in the regulatory impact analysis section, we estimate that approximately 90 percent, or 6,064, facilities make payments of premiums for individual market health plans, whether directly, through a parent organization, or through another entity, and therefore, will need to comply with these disclosure requirements. We estimate that approximately 491,500 patients receive services at Medicare-certified facilities. Therefore, on average, each facility provides dialysis services to approximately 73 patients annually. While we expect to detail in forthcoming guidance how dialysis facilities may comply with these requirements, we are providing an example of one type of disclosure, an informational pamphlet, to illustrate potential costs. We note, that we expect dialysis facilities will use various tools for disclosure including but not limited to informational

pamphlets, handouts, etc. It is estimated that each facility will prepare, on average, a 6 page pamphlet that includes all required information. We estimate that an administrative assistant will spend approximately 40 hours (at an hourly rate of \$37.86) on average to research the required information and develop a pamphlet. We estimate it will take an administrative manager (at an hourly rate of \$91.20) 4 hours to review the pamphlet. The total annual burden for each facility will be 44 hours with an equivalent cost of \$1,879.20 ((40 hours x \$37.86 hourly rate) + (4 hours x \$91.20 hourly rate)). In order to print the pamphlet, we estimate that it will cost each facility \$3.00 (for a six page pamphlet at \$0.50 per page). For all 6,064 facilities, the total annual burden will be 266,816 hours (44 hours x 6,064 facilities) with an equivalent cost of approximately \$11,395,469 (\$1,879.20 annual burden cost x 6,064 facilities) and a total materials and printing cost of \$1,328,016. It is anticipated that the burden to prepare the pamphlet will be lower in subsequent years since all that will be needed is to review and update plan information. We estimate that an administrative assistant will spend approximately 32 hours (at an hourly rate of \$37.86) on average to update the information in the pamphlet, and it will take an administrative manager (at an hourly rate of \$91.20) 3 hours to review it. The total annual burden for each facility will be 35 hours with an equivalent cost of approximately \$1,485 ((32 hours x \$37.86 hourly rate) + (3 hours x \$91.20 hourly rate)). The total burden for all facilities will be 212,240 hours (35 hours x 6,064 facilities) with an equivalent cost of approximately \$9,005,768 (\$1,485.12 annual burden cost x 6,064 facilities).

In addition to providing a copy of the pamphlet to the patients, it is assumed that a health care social worker or other patient assistance personnel at each facility will review the information with the patients and obtain a signed acknowledgement form stating that the patient has received this information. We estimate that a lawyer (at an hourly rate of \$131.02) will take

30 minutes to develop an acknowledgement form confirming that the required information was provided to be signed by the ESRD patient. The total burden for all 6,064 facilities to develop the acknowledgement form in the initial year only will be 3,032 hours (0.5 hours x 6,064 facilities) with an equivalent cost of approximately \$397,253 (($\131.02 hourly rate x 0.5 hours) x 6,064 facilities).

We estimate that a health care social worker (at an hourly rate of $\$51.94$) will take an average of 45 minutes to further educate each patient about their coverage options. The social worker will also obtain the patient's signature on the acknowledgement form and save a copy of the signed form for recordkeeping, incurring a materials and printing cost of $\$0.05$ per form. The total annual burden for each facility will be 54.75 hours (0.75 hours x 73 patients) with an equivalent cost of approximately $\$2,844$ ($\$51.94$ hourly rate x 54.75 hours), and approximately $\$4$ in printing and materials cost. The total annual burden for all 6,064 facilities will be 332,004 hours (54.75 hours x 6,064 facilities) with an equivalent cost of approximately $\$17,244,288$ ($\$2,843.72$ annual burden cost x 6,064 facilities), and approximately $\$22,134$ in printing and materials cost.

We will revise the information collection currently approved under OMB Control Number 0938-0386 to account for this additional burden.

2. ICRs Regarding Disclosure of Third Party Premium Payments, or Contributions to Such Payments, to Issuers (§ 494.180(k))

Under § 494.180(k), HHS is implementing a requirement for those dialysis facilities that make payments of premiums for individual market health plans, whether directly, through a parent organization, or through another entity, must ensure issuers are informed of and have agreed to accept the payments for the duration of the plan year.

Based on comments received in response to the RFI, it is assumed that approximately 7,000 patients that receive such payments are enrolled in individual market plans. Therefore, we estimate that 6,064 facilities will be required to send approximately 7,000 notices. It is assumed that these notices will be sent and returned electronically at minimal cost. We estimate that, for each facility during the initial year, it will take a lawyer one hour (at an hourly rate of \$131.02) to draft a letter template notifying the issuer of third party payments and requesting assurance of acceptance for such payments. The total annual burden for all facilities during the initial year will be 6,064 hours with an equivalent cost of approximately \$794,505 ($\$131.02 \times 6,064$ facilities). This is likely to be an overestimation since parent organizations will probably develop a single template for all individual facilities they own. We further estimate that it will require an administrative assistant approximately 30 minutes (at an hourly rate of \$37.86) to insert customized information and email the notification to the issuer, send any follow-up communication, and then save copies of the responses for recordkeeping. The total annual burden for all facilities for sending the notifications will be 3,500 hours (7,000 notifications \times 0.5 hours) with an equivalent cost of \$132,510 ($\37.86 hourly rate \times 3,500 hours).

There are an estimated 468 issuers in the individual market. It is assumed that the approximately 7,000 patients are uniformly distributed between these issuers. Issuers will incur a burden if they respond to the notifications from dialysis facilities and inform them whether or not they will accept third party payments. It is estimated that it will take a lawyer 30 minutes (at an hourly rate of \$131.02) to review the notification and an administrative manager 30 minutes (at an hourly rate of \$91.20) to approve or deny the request and respond to any follow-up communication. It will further take an administrative assistant approximately 30 minutes (at an hourly rate of \$37.86) to respond electronically to the initial notification and any follow-up

communications. The total annual burden for all issuers to respond to 7,000 notifications will be 10,500 hours (1.5 hours x 7,000 notifications) with an equivalent cost of \$910,280 (10,500 hours x \$86.69 average hourly rate per notification per issuer).

We will revise the information collection currently approved under OMB Control Number 0938–0386 to account for this additional burden.

Table 1: Annual Reporting, Recordkeeping and Disclosure Burden: First Year

Regulation Section(s)	OMB Control No.	Number of respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting (\$)	Total Labor Cost of Reporting (\$)	Total Capital/Maintenance Costs (\$)	Total Cost (\$)
Patient Rights (§ 494.70 (c)) 0 Pamphlets	0938–0386	6,064	442,672	44	266,816	\$42.71	\$11,395,468.80	\$1,328,016.00	\$12,723,484.80
Patient Rights (§ 494.70 (c)) - Patient Education and Recordkeeping	0938–0386	6,064	442,672	0.75	332,004	\$51.94	\$17,244,287.76	\$22,133.60	\$17,266,421.36
Patient Rights (§ 494.70 (c)) - acknowledgement form	0938–0386	6,064	6,064	0.5	3,032	\$131.02	\$397,252.64	\$0.00	\$397,252.64
Disclosure of Third Party Premium Assistance to Issuers (§ 494.180(k)) - letter template	0938–0386	6,064	6,064	1	6,064	\$131.02	\$794,505.28	\$0.00	\$794,505.28
Disclosure of Third Party Premium Assistance to Issuers (§ 494.180(k)) - notification from facility	0938–0386	6,064	7,000	0.5	3,500	\$37.86	\$132,510	\$0.00	\$132,510
Disclosure of Third Party Premium Assistance to Issuers (§ 494.180(k)) - issuer response	0938–0386	468	7,000	1.5	10,500	\$86.69	\$910,280	\$0.00	\$910,280
Total		6,532	911,472	48.25	621,916	\$481.24	\$30,874,304.48	\$1,350,149.60	\$32,224,454.08

Table 2: Annual Reporting, Recordkeeping and Disclosure Burden: Subsequent Years

Regulation Section(s)	OMB Control No.	Number of respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting (\$)	Total Labor Cost of Reporting (\$)	Total Capital/Maintenance Costs (\$)	Total Cost (\$)
Patient Rights (§ 494.70 (c)) 0 Pamphlets	0938–0386	6,064	442,672	35	212,240	\$42.43	\$9,005,767.68	\$1,328,016.00	\$10,333,783.68
Patient Rights (§ 494.70 (c)) - Patient Education and Recordkeeping	0938–0386	6,064	442,672	0.75	332,004	\$51.94	\$17,244,287.76	\$22,133.60	\$17,266,421.36
Disclosure of Third Party Premium Assistance to Issuers (§ 494.180(k)) - notification from facility	0938–0386	6,064	7,000	0.5	3,500	\$37.86	\$132,510.00	\$0.00	\$132,510.00
Disclosure of Third Party Premium Assistance to Issuers (§ 494.180(k)) - issuer response	0938–0386	468	7,000	1.5	10,500	\$86.69	\$910,280.00	\$0.00	\$910,280.00
Total		6,532	899,344	37.75	558,244	\$218.93	\$27,292,845.44	\$1,350,149.60	\$28,642,995.04

If you comment on these information collection requirements, please do either of the following:

1. Submit your comments electronically as specified in the ADDRESSES section

of this interim final rule with comment; or

2. Submit your comments to the Office of Information and Regulatory Affairs,

Office of Management and Budget, Attention: CMS Desk Officer, CMS-3337-IFC. Fax: (202)

395–6974; or Email: OIRA_submission@omb.eop.gov.

V. Regulatory Impact Analysis

A. Introduction

This interim final rule with comment implements a number of requirements for Medicare-certified dialysis facilities that make payments of premiums for individual market health plans, whether directly, through a parent organization, or through another entity. It establishes a new patient rights standard applicable only to such facilities that they must provide patients with information on available health insurance options, including locally available individual market plans, Medicare, Medicaid, and CHIP coverage. This information must include the effects each option will have on the patient's access to, and costs for the providers and suppliers, services, and prescription drugs that are currently within the individual's ESRD plan of care as well as those likely to result from other documented health care needs. This must include an overview of the health-related and financial risks and benefits of the individual market plans available to the patient (including plans offered through and outside the Exchange). Patients must also receive information about all available financial assistance for enrollment in an individual market health plan and the limitations and associated risks of such assistance; including any and all current information about the facility's, or its parent organization's contributions to patients or third parties that subsidize enrollment in individual market health plans for individuals on dialysis.

In addition, the interim final rule with comment establishes a new standard requiring dialysis facilities that make payments of premiums for individual market health plans, whether directly, through a parent organization, or through another entity, to disclose these payments to applicable issuers and requiring the contributing facility to obtain assurance from the issuer that the issuer will accept such payments for the duration of the plan year.

These requirements are intended to ensure that patients are able to make coverage decisions based on full, accurate information, and are not inappropriately influenced by financial interests of dialysis facilities and suppliers, and to minimize the likelihood that coverage is interrupted midyear for these vulnerable patients.

B. Statement of Need

This interim final rule with comment addresses concerns raised by commenters and by HHS regarding the inappropriate steering of patients with ESRD, especially those eligible for Medicare and Medicaid, into individual market health plans that offer significantly higher reimbursement rates compared to Medicare and Medicaid, without regard to the potential risks incurred by the patient. As discussed previously in the preamble, public comments received in response to the August 2016 RFI indicated that dialysis facilities may be encouraging patients to move from one type of coverage into another based solely on the financial benefit to the dialysis facility, and without transparency about the potential consequences for the patient, in circumstances where these actions may result in harm to the individual¹⁹. Further, enrollment trends indicate that the number of individual market enrollees with ESRD more than doubled between 2014 and 2015, which is not itself evidence of inappropriate behavior but does raise concerns that the steering behavior described by commenters may be becoming increasingly common, and without immediate rulemaking patients are at considerable risk of harm.

¹⁹ Individuals who are already covered by Medicare generally cannot become enrolled in coverage in the individual market. Section 1882(d)(3) of the Social Security Act makes it unlawful to sell or issue a health insurance policy (including policies issued on and off Exchanges) to an individual entitled to benefits under Medicare Part A or enrolled under Medicare part B with the knowledge that the policy duplicates the health benefits to which the individual is entitled. Therefore, while an individual with ESRD is not required to apply for and enroll in Medicare, once they become enrolled, it is unlawful for them to be sold a commercial health insurance policy in the individual market if the seller knows the individual market policy would duplicate benefits to which the individual is entitled. The financial consequences for patients moving from Medicare to private insurance—including late enrollment penalties for individuals in Medicare Part A but not Part B if they return to Medicare, and lack of coverage for certain drugs following a kidney transplant—are routinely not disclosed and may be unknown to patients. These financial consequences can have significant impact on patient care.

This interim final rule with comment addresses these issues by implementing a number of requirements that will provide patients with the information they need to make informed decisions about their coverage and will help to ensure that their care is not at risk of disruptions, gaps in coverage, limited access to necessary treatment, or undermined by the providers' or suppliers' financial interests.

C. Overall Impact

We have examined the effects of this rule as required by Executive Order 12866 (58 FR 51735, September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (58 FR 51735) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 (76 FR 3821, January 21, 2011) is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866.

Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule --(1) having an annual effect on the economy of \$100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency;

(3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year. We estimate that this rulemaking is "economically significant" as measured by the \$100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared an RIA that to the best of our ability presents the costs and benefits of the rulemaking.

D. Impact Estimates and Accounting Table

In accordance with OMB Circular A-4, Table 3 below depicts an accounting statement summarizing HHS' assessment of the benefits, costs, and transfers associated with this regulatory action. The period covered by the RIA is 2017 through 2026.

HHS anticipates that the provisions of this interim final rule with comment will enhance patient protections and enable patients with ESRD to choose health insurance coverage that best suits their needs and improve their health outcomes. Providing patients with accurate information will help to ensure that patients are able to obtain necessary health care, reduce the likelihood of coverage gaps, as well as provide financial protection. Dialysis facilities and issuers will incur costs to comply with these requirements. If patients covered through individual market plans opt to move to (or return to) Medicare and Medicaid, then there will be a transfer of patient care costs to the Medicare and Medicaid programs. For those patients covered through individual market plans who chose to apply for and enroll in Medicare, there would be a transfer of premium payments from individual market issuers to the Medicare program. In accordance with Executive Order 12866, HHS believes that the benefits of this regulatory action

justify the costs.

Table 3: Accounting Table

Benefits:				
Qualitative:				
* Provide patient protections and ensure that patients are able to make coverage decisions based on complete and accurate information, and are not inappropriately influenced by the financial interests of dialysis facilities.				
* Improve health outcomes for patients by ensuring that patients have coverage that best fits both current and future needs, including transplantation services.				
* Ensure that issuers will accept any premium assistance payments for the duration of the plan year and patients' coverage is not interrupted midyear.				
Costs:	Estimate	Year dollar	Discount rate percent	Period covered
Annualized Monetized	\$29.1 million	2016	7	2017-2026
	\$29.1 million	2016	3	2017-2026
Costs reflect administrative costs incurred by dialysis facilities and issuers to comply with ICRs.				
Transfers:	Estimate	Year dollar	Discount rate percent	Period covered
Annualized Monetized	\$688.4 million	2016	7	2017-2026
	\$688.4 million	2016	3	2017-2016
Transfers reflect transfer of patient care costs from individual market issuers to Medicare and Medicaid; out-of-pocket costs from dual eligible patients to Medicare and Medicaid; transfer of premium dollars from individual market issuers to Medicare; and transfer of reimbursements from dialysis facilities to individual market issuers if patients move from individual market plans to Medicare and Medicaid.				

a. Number of Affected Entities

There are 6,737 dialysis facilities across the country that are certified by Medicare, and an estimated 495,000 patients on dialysis. Based on USRDS data for recent years, we estimated that approximately 99.3 percent or 491,500 patients receive services at Medicare-certified facilities. Therefore, each Medicare-certified facility is providing services to approximately 73 patients on average annually. As mentioned previously, data indicates that about 88 percent of ESRD patients receiving hemodialysis were covered by Medicare (as primary or secondary payer) in 2014. Data from the CMS risk adjustment program in the individual market (both on

and off exchange) suggest that the number of enrollees with an ESRD diagnosis in the individual market more than doubled between 2014 and 2015. Although some of the increase could be due to increases in coding intensity and cross-year claims, the gross number is still significant and concerning. Comments received in response to the RFI suggest that the inappropriate steering of patients may be accelerating over time. Insurance industry commenters stated that the number of patients in individual market plans receiving dialysis increased 2 to 5 fold in recent years. We will continue to analyze these data to better understand trends in ESRD diagnoses as well as the extent to which individuals may be enrolled in both Medicare and individual market plans and implications for the anti-duplication provision outlined in section 1882(d)(3) of the Act.

There is no data on how many dialysis facilities make payments of premiums for individual market health plans, whether directly, through a parent organization, or through another entity. We believe that these practices are likely concentrated within large dialysis chains that together operate approximately 90 percent of dialysis facilities, and therefore estimate that approximately 6,064 facilities make payments of premiums for individual market health plans, whether directly, through a parent organization, or through another entity.

b. Anticipated Benefits, Costs and Transfers

This interim final rule with comment implements a number of requirements for Medicare-certified dialysis facilities (as defined in 42 CFR 494.10) that make payments of premiums for individual market health plans (in any amount), whether directly, through a parent organization (such as a dialysis corporation), or through another entity (including by providing contributions to entities that make such payments). Such facilities must provide patients with information on available health coverage options, including local, current individual market plans, Medicare, Medicaid, and CHIP coverage. This information must include; the effects each

coverage option will have on the patient's access to, and costs for, the providers and suppliers, services, and prescription drugs that are currently within the individual's ESRD plan of care as well as those likely to result from other documented health care needs. This must include an overview of the health-related and financial risks and benefits of the individual market plans available to the patient (including plans offered through and outside the Exchange). Information on coverage of transplant-associated costs must also be provided to patients, including pre- and post-transplant care. In addition, facilities must provide information about penalties associated with late enrollment in Medicare. Patients must also receive information about available financial assistance for enrollment in an individual market health plan and limitations and associated risks of such assistance; the financial benefit to the facility of enrolling the individual in an individual market plan as opposed to public plans; and current information about the facility's, or its parent organization's contributions to patients or third parties that make payments of premiums for individual market plans for individuals on dialysis.

These requirements are intended to ensure that patients are able to make insurance coverage decisions based on full, accurate information, and not based on misleading, inaccurate, or incomplete information that prioritizes providers and suppliers' financial interests. It is likely that some patients will elect to apply for and enroll in Medicare and Medicaid (if eligible) instead of individual market plans once they are provided all the information as required. As previously discussed, Medicare (and Medicaid) enrollment will provide health benefits by reducing the likelihood of disruption of care, gaps in coverage, limited access to necessary treatment, denial of access to kidney transplants or delay in transplant readiness, and denial of post-surgical care. By enrolling in Medicare (and Medicaid), many individuals can avoid potential financial loss due to Medicare late enrollment penalties; higher cost-sharing, especially for out-of-network

services; higher deductibles; and coverage limits in individual market plans. This is particularly true for the individuals eligible for Medicare based on ESRD who are also eligible for Medicaid. While a patient with individual market coverage could be liable for out-of-pocket costs of up to \$7,150 in 2017, a patient dually enrolled in Medicare and Medicaid will have very limited, and in many cases no, out-of-pocket costs in addition to a wider range of eligible providers and suppliers.

In addition, this interim final rule with comment establishes a new standard, applicable only to facilities that make payments of premiums for individual market health plans, whether directly, through a parent organization (such as a dialysis corporation), or through another entity (including by providing contributions to entities that make such payments), requiring that the facility disclose such payments to applicable issuers and obtain assurance from the issuer that they will accept such payments for the duration of the plan year. This will lead to improved health outcomes for patients by ensuring that coverage is not interrupted midyear for these vulnerable patients, leaving them in medical or financial jeopardy.

Dialysis facilities that make premium payments for patients as discussed above will incur costs to comply with the provisions of this rule. The administrative costs related to the disclosure requirements have been estimated in the previous section.

If patients elect to apply for and enroll in Medicare and Medicaid (if eligible) instead of individual market plans, the cost of their coverage will be transferred from the patients and the individual market issuers to the Medicare and Medicaid programs (if the patient is eligible for both). This will lead to increased spending for these programs. For the purpose of this analysis, we assume that approximately 50 percent of patients enrolled in individual market plans that receive third party premium payments will elect to apply for and enroll in Medicare. USRDS

data show that for individuals with ESRD enrolled in Medicare receiving hemodialysis, total health care spending averaged \$91,000 per person in 2014, including dialysis and non-dialysis services. Therefore, if 3,500 patients switch to Medicare, the total transfer from individual market issuers to the Medicare program will be approximately \$318,500,000. We assume that about 50 percent of patients that opt to enroll in Medicare will also be eligible for Medicaid and will have negligible or zero cost-sharing, rather than the maximum out-of-pocket cost of \$7,150, which will be a transfer from the patients to the Medicare and Medicaid programs. Therefore, for 1,750 dual eligible patients, the total transfer is estimated to be \$12,512,500. For those patients covered through individual market plans who choose to enroll in Medicare there will also be a transfer of premium payments from the individual market issuers to the Medicare program. Assuming that patients will pay the standard Part B premium amount, which will be \$134 in 2017, and an average Part D premium of \$42.17²⁰, the total transfer for 3,500 patients is estimated to be \$7,399,140. In addition, if patients move from individual market plans to Medicare, then reimbursements to dialysis facilities will be reduced, since individual market plans currently have higher reimbursement rates for dialysis services compared to Medicare, resulting in a transfer from dialysis facilities to issuers. As discussed previously, based on comments received, dialysis facilities are estimated to be paid at least \$100,000 more per year per patient for a typical patient enrolled in commercial coverage rather than public coverage. For 3,500 patients, the total transfer from dialysis facilities to issuers is estimated to be at least \$350,000,000.

E. Alternatives Considered

20 Source: Jack Hoadley et al., Medicare Part D: A First Look at Prescription Drug Plans in 2017, Kaiser Family Foundation, October 2016, <http://kff.org/medicare/issue-brief/medicare-part-d-a-first-look-at-prescription-drug-plans-in-2017/>.

Under the Executive Order, HHS is required to consider alternatives to issuing rules and alternative regulatory approaches. HHS considered not requiring any additional disclosures to patients. Providing complex information regarding available coverage options may not always help patients make the best decisions. In addition, disclosure requirements may not be as effective where financial conflicts of interest remain for the dialysis facilities. We also considered prohibiting outright contributions from dialysis suppliers to patients or third parties for individual market plan premiums, but determined that we wanted to have additional data before implementing additional restrictions. A ban could potentially cause financial hardship for some patients. On the other hand, dialysis facilities would not be able to use these contributions to steer patients towards individual market plans that are more in the financial interests of dialysis facilities rather than those of the patient. In the absence of additional data, it is not possible to estimate the costs, benefits and transfers associated with such a ban, whether the benefits would outweigh the costs, and whether it would be more effective in ending the practice of steering.

HHS believes, however, that patients will benefit from having complete and accurate information regarding their options, especially information on Medicare and Medicaid and the financial and medical/coverage consequences of each option. In addition, CMS can ensure compliance with the disclosure requirements through the survey and certification process. CMS plans to issue interpretive guidance and a survey protocol for the enforcement of the new standards by state surveyors to ensure that the facilities share appropriate information with patients.

We also considered requiring issuers to accept all third party premium payments. However, requiring issuers to accept such payments could skew the individual market risk pool,

a position CMS has consistently articulated since 2013, when we expressly discouraged issuers from accepting these premium payments from providers. We also received comments from issuers, social workers, and others in response to the RFI indicating that inappropriate steering practices could have the effect of skewing the insurance risk pool. The underlying policy considerations have not changed and therefore CMS is seeking to prevent mid-year disruption by requiring facilities to disclose payments and assure acceptance. In light of the comments received regarding dialysis facilities' practices in particular, and the unique health needs and coverage options available to this population, we are at this time imposing disclosure-related obligations only on the ESRD facilities themselves. This rule does not change the legal obligations or requirements placed on issuers.

In addition, to determine whether further action is warranted, we seek comments from stakeholders on whether patients would be better off on balance if premium assistance originating from health care providers and suppliers were more strictly limited and disclosed. We also seek comment on alternative options where payments would be limited absent a showing that the individual market coverage was in the individual's best interest, and we seek comment on what such a showing would require and how it could prevent mid-year disruptions in coverage.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 et seq.) and that are likely to have a significant economic impact on a substantial number of small entities. Unless an agency certifies that a rule is not likely to have a significant economic impact on a

substantial number of small entities, section 604 of RFA requires that the agency present a final regulatory flexibility analysis describing the impact of the rule on small entities and seeking public comment on such impact.

The RFA generally defines a “small entity” as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA) (13 CFR 121.201); (2) a nonprofit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. (States and individuals are not included in the definition of “small entity.”) HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

Because this provision is issued as a final rule without being preceded by a general notice of proposed rulemaking, a final regulatory analysis under section 604 of the Regulatory Flexibility Act (94 Stat. 1167) is not required. Nevertheless, HHS estimates that approximately 10 percent of Medicare-certified dialysis facilities are not part of a large chain and may qualify as small entities. It is not clear how many of these facilities make payments of premiums for individual market health plans, whether directly, through a parent organization, or through another entity. To the extent that they do so, these facilities will incur costs to comply with the provisions of this interim final rule with comment and experience a reduction in reimbursements if patients transfer from individual market coverage to Medicare. However, HHS believes that very few small entities, if any, make such payments. Therefore, HHS expects that this interim final rule with comment will not affect a substantial number of small entities. Accordingly, the Secretary certifies that a regulatory flexibility analysis is not required.

In addition, section 1102(b) of the Social Security Act requires agencies to prepare a regulatory impact analysis if a rule may have a significant economic impact on the operations of

a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. This interim final rule with comment will not affect small rural hospitals. Therefore, HHS has determined that this regulation will not have a significant impact on the operations of a substantial number of small rural hospitals.

G. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that includes a Federal mandate that could result in expenditure in any one year by state, local or tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold level is approximately \$146 million.

UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of cost, mainly those “Federal mandate” costs resulting from--(1) imposing enforceable duties on state, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, state, local, or tribal governments under entitlement programs.

This interim final rule with comment includes no mandates on state, local, or tribal governments. Thus, this rule does not impose an unfunded mandate on state, local or tribal governments. As discussed previously, dialysis facilities that wish to make payments of premiums for individual market health plans (in any amount), whether directly, through a parent organization (such as a dialysis corporation), or through another entity (including by providing contributions to entities that make such payments), will incur administrative costs in order to comply with the provisions of this interim final rule with comment. Issuers will incur some administrative costs as well. However, consistent with policy embodied in UMRA, this interim

final rule with comment has been designed to be the least burdensome alternative for state, local and tribal governments, and the private sector.

H. Federalism

Executive Order 13132 outlines fundamental principles of federalism. It requires adherence to specific criteria by Federal agencies in formulating and implementing policies that have “substantial direct effects” on the states, the relationship between the national government and states, or on the distribution of power and responsibilities among the various levels of government.

This rule does not have direct effects on the states, the relationship between the Federal government and states, or on the distribution of power and responsibilities among various levels of government.

I. Congressional Review Act

This interim final rule with comment is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.), which specifies that before a rule can take effect, the Federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and has been transmitted to the Congress and the Comptroller General for review.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 494

Health facilities, Incorporation by reference, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as follows:

PART 494—CONDITIONS FOR COVERAGE FOR END-STAGE RENAL DISEASE FACILITIES

1. The authority citation for part 494 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. Section 494.70 is amended by redesignating paragraph (c) as paragraph (d) and adding a new paragraph (c) to read as follows:

§ 494.70 Condition: Patients' rights.

* * * * *

(c) Standard: Right to be informed of health coverage options. For patients of dialysis facilities that make payments of premiums for individual market health plans (in any amount), whether directly, through a parent organization (such as a dialysis corporation), or through another entity (including by providing contributions to entities that make such payments), the patient has the right to—

(1) Be informed annually, on a timely basis for each plan year, of all available health coverage options, including but not limited to Medicare, Medicaid, CHIP and individual market plans. This must include information on:

(i) How plans in the individual market will affect the patient's access to, and costs for the providers and suppliers, services, and prescription drugs that are currently within the individual's ESRD plan of care as well as those likely to result from other documented health care needs.

This must include an overview of the health-related and financial risks and benefits of the

individual market plans available to the patient (including plans offered through and outside the Exchange).

(ii) Medicare and Medicaid/Children's Health Insurance Coverage (CHIP) coverage, including Medicare Savings Programs, and how enrollment in those programs will affect the patient's access to and costs for health care providers, services, and prescription drugs that are currently within the individual's plan of care.

(iii) Each option's coverage and anticipated costs associated with transplantation, including patient and living donor costs for pre- and post-transplant care.

(2) Receive current information from the facility about premium assistance for enrollment in an individual market health plan that may be available to the patient from the facility, its parent organization, or third parties, including but not limited to limitations and any associated risks of such assistance.

(3) Receive current information about the facility's, or its parent organization's, contributions to patients or third parties that subsidize the individual's enrollment in individual market health plans for individuals on dialysis, including the reimbursements for services rendered that the facility receives as a result of subsidizing such enrollment.

* * * * *

3. Section 494.180 is amended by adding a new paragraph (k) to read as follows:

§ 494.180 Condition: Governance.

* * * * *

(k) Standard: Disclosure to Insurers of Payments of Premiums. (1) Facilities that make payments of premiums for individual market health plans (in any amount), whether directly,

through a parent organization (such as a dialysis corporation), or through another entity (including by providing contributions to entities that make such payments) must—

(i) Disclose to the applicable issuer each policy for which a third party payment described in this paragraph (k) will be made, and

(ii) Obtain assurance from the issuer that the issuer will accept such payments for the duration of the plan year. If such assurances are not provided, the facility shall not make payments of premiums and shall take reasonable steps to ensure such payments are not made by the facility or by third parties to which the facility contributes as described in this paragraph (k).

(2) If a facility is aware that a patient is not eligible for Medicaid and is not eligible to enroll in Medicare Part A and/or Part B except during the General Enrollment Period, and the facility is aware that the patient intends to enroll in Medicare Part A and/or Part B during that period, the standards under this paragraph (k) will not apply with respect to payments for that patient until July 1, 2017.

Dated: November 28, 2016

Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

Dated: November 29, 2016

Sylvia M. Burwell,

Secretary,

Department of Health and Human Services.

BILLING CODE 4120-01-P

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