or apply to the Quality Payment Program.

2. Commercially Reasonable (§ 411.351)

We are proposing to include at § 411.351 a definition for the term "commercially reasonable." As described previously, many of the statutory and regulatory exceptions to the physician self-referral law include a requirement that the compensation arrangement is commercially reasonable. For example, the exception at section 1877(e)(2) of the Act for *bona fide* employment relationships requires that the remuneration provided to the physician is pursuant to an arrangement that would be commercially reasonable (even if no referrals were made to the employer). The exception at section 1877(e)(3)(A) of the Act for personal service arrangements uses slightly different language to describe this general concept, and requires that the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement. The exception at § 411.357(l) for fair market value compensation, which the Secretary established in regulation using his authority at section 1877(b)(4) of the Act, requires that the arrangement is commercially reasonable (taking into account the nature and scope of the transaction) and furthers the legitimate business purposes of the parties. Despite the prevalence of this requirement (in one form or another), we addressed the concept of commercial reasonableness only once—in our 1998 proposed rule—where we stated that we are interpreting "commercially reasonable" to mean that an arrangement appears to be a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals (63 FR 1700). The physician self-referral regulations themselves lack a codified definition for the term commercially reasonable.

As discussed previously, we believe that the key question to ask when determining whether an arrangement is commercially reasonable is simply whether the arrangement makes sense as a means to accomplish the parties' goals. We continue to believe that this determination should be made from the perspective of the particular parties involved in the arrangement. The determination of commercial reasonableness is not one of valuation. Nor does the determination that an arrangement is commercially reasonable turn on whether the arrangement is profitable. It is apparent from our review of the CMS RFI comments that there is a widespread misconception about our position on the nexus between the commercial reasonableness of an arrangement and its profitability. We wish to clarify that compensation arrangements that do not result in profit for one or more of the parties may nonetheless be commercially reasonable.

CMS RFI commenters shared numerous examples of compensation arrangements that they believed would be commercially reasonable despite the fact that the party paying the remuneration does not recognize an equivalent or greater financial benefit from the items or services purchased in the transaction, or that the party receiving the remuneration incurs costs in furnishing the items or services that are greater than the amount of the remuneration received. Commenters also explained that, even knowing in advance that an arrangement may result in losses to one or more parties, it may be reasonable, if not necessary, to nevertheless enter into the arrangement. These commenters explained some of the reasons why parties would enter into such transactions, such as community need, timely access to health care services, fulfillment of licensure or regulatory obligations, including those under the Emergency Medical Treatment and Labor Act (EMTALA), the provision of charity care, and the improvement of quality and health outcomes. One commenter suggested that entire hospital service lines, with their needed management and other physician-provided services, are illustrative for operating at a loss and identified psychiatric and burn units as examples of such service lines. According to this commenter, with changes in reimbursement, more service lines will operate at a loss in the future. The commenter urged that these services are of vital need to communities and, unless CMS addresses the definition of "commercial reasonableness," health care providers may be prohibited from providing these services to their communities as a result of a fear of violating the commercial reasonableness standard. We find these comments and the concerns they highlight compelling.

We are proposing two alternative definitions for the term "commercially reasonable." First, we are proposing to define "commercially reasonable" to mean that the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements. In the alternative, we are proposing to define "commercially reasonable" to mean that the arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty. We seek comment on each of these proposed definitions as well as input from stakeholders regarding other possible definitions that would provide clear guidance to enable parties to structure their arrangements in a manner that ensures compliance with the requirement that their particular arrangement is commercially reasonable. We are also proposing to clarify in regulation text that an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.

In developing our proposals, we reviewed the Internal Revenue Service (IRS) Revenue Ruling 97–21, which considered whether a hospital violates the requirements for exemption from federal income tax as an organization described in section 501(c)(3) of the Internal Revenue Code (Title 26 of the United States Code) when it provides incentives to recruit private practice physicians to join its medical staff or to provide medical services in the community. The IRS identified several activities that would support a hospital's charitable purposes, all of which were mentioned in the CMS RFI comments. As described previously, the arrangements identified by commenters on the CMS RFI may further a legitimate business purpose of the parties or make commercial sense as well. However, arrangements that, on their face, appear to further a legitimate business purpose of the parties may not be commercially reasonable if they merely duplicate other facially legitimate arrangements. For example, a hospital may enter into an arrangement for the personal services of a physician to oversee its oncology department. If the hospital needs only one medical director for the oncology department, but later enters into a second arrangement with another physician for oversight of the department, the second arrangement merely duplicates the already-obtained medical directorship services and may not be commercially reasonable. Although the evaluation of compliance with the physician self-referral law always requires a review of the facts and circumstances of the financial relationship between the parties, the commercial reasonableness of multiple arrangements for the same services is questionable.

Also important to our consideration of the best way to define and interpret "commercially reasonable" was the IRS's conclusion that a hospital may not engage in substantial unlawful activities and maintain its tax-exempt status

because the conduct of an unlawful activity is inconsistent with charitable purposes. The IRS explained that an organization conducts an activity that is unlawful, and therefore not in furtherance of a charitable purpose, if the organization's property is to be used for an objective that is in violation of the criminal law. We are similarly taking the position that an activity that is in violation of criminal law would not be a legitimate business purpose of the parties, nor would it make commercial sense, and, therefore, would not be commercially reasonable for purposes of the physician self-referral law. We note that the absence of a criminal violation would not, in and of itself, establish that an arrangement is commercially reasonable. We seek comment on our alternate proposals for the definition of "commercially reasonable" and its interpretation, including how parties could determine whether an arrangement is on similar terms and conditions as like arrangements.

We note that many of the exceptions to the physician self-referral law require that an arrangement is commercially reasonable "even if no referrals were made between the parties" or "even if no referrals were made to the employer." The exceptions use varying phrasing to describe this requirement and we do not repeat each iteration here. We are not proposing to eliminate this requirement from the exceptions where it appears. For example, under our first alternative proposal, an employment arrangement must further a legitimate business purpose of the parties and be on similar terms and conditions as like arrangements, even if no referrals were made to the employer, as well as satisfy the other requirements of the exception, in order for the physician to refer patients to the employing entity for designated health services and for the employing entity to submit claims to Medicare for the referred designated health services. Under our second alternative proposal, an employment arrangement must make commercial sense and be entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty, even if no referrals were made to the employer, as well as satisfy the other requirements of the exception. To emphasize, a compensation arrangement must satisfy the "even if no referrals were made" requirement if it is included as a requirement of the relevant exception under which the parties seek protection from the physician self-referral law's referral and claims submission prohibitions.

3. The Volume or Value Standard and the Other Business Generated Standard (§ 411.354(d)(5) and (6))

Many of the exceptions at section 1877(e) of the Act ("Exceptions Relating to Other Compensation Arrangements") and in our regulations include a requirement that the compensation paid under the arrangement is not determined in a manner that takes into account the volume or value of referrals by the physician who is a party to the arrangement, and some exceptions also include a requirement that the compensation is not determined in a manner that takes into account other business generated between the parties. We refer to these as the "volume or value standard" and the "other business generated standard," respectively. Throughout the regulatory history of the physician self-referral law, we have shared our interpretation of these standards and responded to comments as they arose. Despite our attempt at establishing clear guidance regarding the application of the volume or value standard and the other business generated standard, commenters to several requests for information, including the CMS RFI, identified their lack of a clear understanding as to when compensation will be considered to take into account the volume or value of referrals or other business generated by the physician as one of the greatest risks they face when structuring arrangements between entities furnishing designated health services and the physicians who refer to them. They stated that, not only do they face the risk of penalties under the physician self-referral law, but, because a violation of the physician self-referral law may be the predicate for liability under the Federal False Claims Act (31 U.S.C. 3729 through 3733), entities are susceptible to both government and whistleblower actions that can result in significant penalties through litigation or settlement. Commenters and other stakeholders have long expressed frustration that, from their perspective, the guidance from CMS has been too limited and left them without an objective standard against which to judge their financial relationships. Our proposals here are intended to provide objective tests for determining whether compensation takes into account the volume or value of referrals or the volume or value of other business generated by the physician. Before describing our proposals, we provide a brief history of the guidance to date on the volume or value standard and the other business generated standard.

In the 1998 proposed rule, we discussed the volume or value standard as it pertains to the criteria that a physician practice must meet to qualify as a "group practice" (63 FR 1690). We also stated that we would apply this interpretation of the volume or value standard throughout our regulations (63 FR 1699). In the discussion of group practices, we stated that we believe that the volume or value standard precludes a group practice from paying physician members for each referral they personally make or based on the volume or value of the referred services (63 FR 1690). We went on to state that the most straightforward way for a physician practice to demonstrate that it is meeting the requirements for group practices would be for the practice to avoid a link between physician compensation and the volume or value of any referrals, regardless of whether the referrals involve Medicare or Medicaid patients (63 FR 1690). However, because our definition of "referral" at § 411.351 includes only referrals for designated health services, we also noted that a physician practice that wants to compensate its members on the basis of non-Medicare and non-Medicaid referrals would be required to separately account for revenues and distributions related to referrals for designated health services for Medicare and Medicaid patients (63 FR 1690). (See section II.C. of this proposed rule for a discussion of the inclusion of Medicaid referrals in the existing regulation and our proposed revisions to the group practice rules.) Outside of the group practice context, these principles apply generally to compensation from an entity to a physician. We also addressed the other business generated standard in the 1998 proposed rule, stating that we believe that the Congress may not have wished to except arrangements that include additional compensation for other business dealings and that, if a party's compensation contains payment for other business generated between the parties, we would expect the parties to separately determine if this extra payment falls within one of the exceptions (63 FR 1700).

In Phase I, we finalized our policy regarding the volume or value standard and the other business generated standard, responding to comments on our proposals in the 1998 proposed rule. Most importantly, we revised the scope of the volume or value standard to permit time-based or unit of service-based compensation formulas (66 FR 876). We also stated that the phrase "does not take into account other