

Agreements Filed with the Federal Trade Commission under the Medicare

some period of time including four no-AG commitments with first filers.

Eight additional final settlements are categorized as containing “possible compensation” because it is not clear from the face of each settlement agreement whether certain provisions act as compensation to the generic patent challenger. For example, an agreement containing a declining royalty structure, in which the generic’s obligation to pay royalties is reduced or eliminated if a brand launches an authorized generic product, may achieve the same effect as an explicit no-AG commitment. Analysis of whether there is compensation requires inquiry into specific marketplace circumstances, which lies beyond the scope of this summary report. Each of these settlements also contained a restriction on generic entry.

111 of the 160 final settlements restrict the generic manufacturer’s ability to market its product but contain no explicit or possible compensation.

20 final settlements contain no restriction (h)(n)2(a)s

The number of potential payfor-delay agreements in FY 2014 declined to 21, representing a substantial decrease from the record high of 40 potential payfor-delay settlements filed in FY 2012 and also a sizable reduction from other recent years, including FY 2013 (29 such agreements), FY 2011 (28) and FY 2010 (31)

The number of potential payfor-delay settlements involving first filers (11) in FY 2014 was the lowest since 2007, when there were only 33 total final settlements for the entire fiscal year. As recently as FY 2012, the number of potential payfor-delay settlements involving first filers was more than double (23) the number seen this year. Other recent years also saw larger numbers of potential payfor-delay settlements involving first filers, including FY 2011 (18 such agreements) and FY 2013 (13).

As in FY 2013, the number of potential payfor-delay settlements involving a no-AG commitment as a form of compensation in FY 2014 was

