

ICCBBA License Fees for Collection Products for Cellular Therapy Manufacturing

ICCBBA Licensing Information

ICCBBA is a not-for-profit Standards Development Organization that is funded entirely from license fees paid by users of the ISBT 128 Standard. The 2021 license fees that will apply to the organizations associated with apheresis collection products are shown below. Fees are reviewed annually.

Apheresis Collection Centers

Apheresis collection centers that are already licensed to use ISBT 128 will be covered by their existing license. They should add the total number of apheresis collection products for further manufacture collected in the year to the total they report on their Facility Annual Return form.

Apheresis collection centers that are not already licensed to use ISBT 128 will need to register as a Cellular Therapy (CT) facility as shown in the table below.

Sponsors/Manufacturers

Sponsors/Manufacturers who will be using the apheresis collection label, but at this stage will not be using ISBT 128 identification on final products, are not required to register with ICCBBA but are recommended to do so to give them access to the ICCBBA help desk. They would register as a CT facility at the lowest fee level.

Sponsors/Manufacturers who intend to use ISBT 128 labeling on final products will need to register as a CT facility, and the fee will be based on the total number of final products distributed that are labeled with ISBT 128, as shown in the table below.

When registered, the Sponsor/Manufacturer is assigned a globally unique Facility Identification Number (FIN) that allows the Sponsor/Manufacturer to assign globally unique Donation Identification Numbers and could act as an Issuing Organization identifier within a Chain of Identity (CoI) identifier. Additional FINs can be purchased if necessary.

Software Providers

Vendors providing software to customers that generates and/or outputs ISBT 128 data structures will need to be registered as software vendors.

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Fee Levels

CT Facility Fees

- Initial registration fee (one-off): USD 200
- Additional FIN: USD 182

Cellular Therapy facilities that only perform collections will be billed based on the total number of Donation Identification Numbers (DINs) assigned annually. DINs are assigned to each collection/pooling event. Facilities that only process units will be billed based on the total number of final ISBT 128 labeled products distributed annually. For facilities that both collect and process, we will bill based on whichever annual total value is greater. The annual bill is calculated as follows:

Annual License Fees

IF	THEN
Your facility assigns \leq 1,000 DINs AND distributes \leq 1,000 ISBT 128 labelled products.	Your annual licensing fee is USD 284
Your facility assigns \leq 20,000 DINs AND distributes \leq 20,000 ISBT 128 labelled products	Your annual licensing fee is USD 433
Your facility assigns $>$ 20,000 DINs OR distributes $>$ 20,000 ISBT 128 labelled products	Your annual licensing fee is USD 433 plus USD 0.018 for each DIN/product over 20,000

Software vendor fees

IF	THEN
You supply software using ISBT 128 to a single customer	Your annual license fee is USD 1,613
You supply software using ISBT 128 to 2-9 customers	Your annual license fee is USD 3,870
You supply software using ISBT 128 to 10-25 customers	Your annual license fee is USD 7,300
You supply software using ISBT 128 to $>$ 25 customers	Your annual license fee is USD 8,120